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INTRAUTERINE DEVICES


Population Information Program, The Johns Hopkins University, Hampton House, 624 North Broadway, Baltimore, Maryland 21205, USA

# IUDs—A New Look


**Editors' Summary.** Using an intrauterine device (IUD) is many times safer than pregnancy and more effective in preventing pregnancy than oral contraceptives, condoms, spermicides, any barrier method, or Natural Family Planning. The current generation of IUDs is safe for most women and about 99 percent effective over one year of use. But not all women should use IUDs. The provider must screen potential users, insert the IUD correctly, and follow up users.


### The TCu-380A

One of the latest generation of IUDs, a copper-bearing, T-shaped device called the TCu-380A, may soon be the major IUD available in most countries. The TCu-380A is becoming the primary IUD provided by the United States Agency for International Development, one of the major international donors of contraceptives. Also, the TCu-380A may be marketed in the US starting in 1988. This IUD will fill the gap in the US created when major manufacturers stopped marketing their IUDs for financial reasons. Both in developing countries and in the US, the TCu-380A will be available at special low prices to governments and nonprofit family planning programs.

The TCu-380A is one of the most effective methods of contraception ever developed. In large multicenter trials pregnancy rates are less than one per 100 women in the first year of use and, in the largest major international study, only 1.4 after *six* years. The TCu-380A and other newer IUDs—the TCu-220C, the Multiload-375, and the Nova T—are more effective in practice than oral contraceptives.

### Safety Issues Clarified

Recent research is helping to lift a cloud that has hung over the IUD for the past several years. Research has shown that IUD use increases the risk of pelvic inflammatory disease (infection in the upper genital tract) and subsequent infertility. Newer studies and new analyses of earlier studies show that the risk of infection is largely limited to the first four months after IUD insertion and to women exposed to sexually transmitted diseases. There appears to be virtually no increased risk of infertility in a woman using a copper IUD who has a mutually faithful sexual relationship with one partner and thus is not exposed to sexually transmitted diseases.

Similarly, evidence shows that copper and all-plastic IUDs do not increase the risk of ectopic pregnancies (that is, pregnancies outside the uterus). In fact, these IUDs provide some protection against them. This finding helps to settle a long-standing debate.

### The Provider's Role

Successful IUD use depends on more than a well-designed and tested IUD. The judgment and skill of the provider are important to ensure:

**(1) Careful screening of women interested in using IUDs.** Women who have or might get sexually transmitted diseases should not use IUDs.

**(2) Careful insertion, carried out under sterile conditions with disinfected instruments, that places the IUD high in the uterus.** This will minimize pain during insertion, the risks of perforation and infection, and the chances of pregnancy and expulsion. An IUD can be inserted at any time during the menstrual cycle.

**(3) Informative and empathetic counseling.** An IUD user needs to know and remember what signs call for medical attention, when a copper or hormone-releasing IUD should be replaced, and that the IUD does not protect against AIDS and other sexually transmitted diseases.

**(4) Regular follow-up plus quick access to medical care.** Help should be available quickly any time an IUD user notices any signs of complications or has any concerns.

Not only doctors but also nurses, midwives, and other health care providers can safely insert IUDs. Whatever their backgrounds, all need special training in pelvic examination and insertion technique and also in screening, counseling, and follow-up. **End of Editors' Summary.**

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## BACKGROUND

Intrauterine devices (IUDs) have been used throughout the world for almost three decades. Millions of women have found them very effective, safe, and convenient. During the 1960s and 1970s researchers developed the "second-generation" copper IUDs, which are highly effective, long-lasting, and have even fewer side effects. Now that these improved IUDs are becoming widely available, attention is shifting toward identifying appropriate IUD users and providing high-quality medical care and counseling to maximize safety and acceptability.

The first modern IUDs—the Lippes Loop and the Margulies Spiral—appeared in the early 1960s. They were made of polyethylene, a biologically inert plastic (137, 216). In the late 1960s researchers discovered that adding copper to a plastic IUD frame increased effectiveness. The first copper IUDs—the Cu-7 and TCu-200—were smaller than the all-plastic devices.

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Thus they caused fewer side effects. But they were just as effective in preventing pregnancy (370, 454). It was thought, however, that these IUDs would have to be replaced every few years. Therefore a second generation of copper IUDs was developed, including the TCu-380A, the TCu-220, the Nova T, the Multiload-375 (MLCu-375), and others (see pp. 16–17). These IUDs are longer lasting and even more effective. IUDs that release a hormone in the uterus also were developed in the 1970s (5).

International donor agencies are now providing second-generation copper IUDs for use in developing-country programs. The United States Agency for International Development (US AID), one of the major international donors of IUDs, began supplying the TCu-380A in 1985 and is now supplying this device to nearly all programs because it is effective and long-lasting (401, 402). The cumulative pregnancy rate after six years of use is just 1.4 per 100 women, according to a World Health Organization (WHO) international study (307). The International Planned Parenthood Federation and some other donor agencies provide the Nova T and Multiloads as well as the TCu-380A. Except in a few countries, notably China, where stainless steel rings are the most widely used IUDs and the TCu-220 is the only second-generation copper IUD in use, the TCu-380A is likely to become the predominant IUD in most developing-country programs.

### US Situation

In the US the TCu-380A will soon be available. Although the US Food and Drug Administration approved its sale in 1984, no pharmaceutical company has marketed it in the US. In late 1987 GynoPharma, Inc., a new US company specializing in gynecologic and contraceptive products, received a license from the Population Council, developers of the TCu-380A, to sell this IUD in the US. GynoPharma is expected to begin marketing in 1988.

The introduction of the TCu-380A in the US will fill a gap created in the mid-1980s when US manufacturers stopped selling the Saf-T-Coil (139), the Lippes Loop (246), and, in 1986, the TCu-200 and the Cu-7 (316). Since the removal of these devices from the market, the hormone-releasing Progestasert has been the only IUD available in the US. This has caused hardships for US women as well as concern in other countries (111).

The reasons for the near absence of IUDs on the US market are unique and complex. They do not involve the safety or efficacy of the IUDs recently taken off the market but instead involve business decisions. In the US, unlike many other countries, family planning services are provided largely through the private sector. For the most part, private pharmaceutical companies sell IUDs for a profit. Because only a small percentage of American women use IUDs—some 7 percent of women in 1982–83 (242)—and because IUDs are long-lasting, profits from any IUD are modest. As more doctors switched to copper IUDs, sales of all-plastic devices declined, leading manufacturers of the Saf-T-Coil and the Lippes Loop to halt production (139, 246).

The Searle Company took the copper Cu-7 and TCu-200 off the market in 1986 for a somewhat different reason. Over 800 lawsuits had been filed against the company, charging that the IUDs had injured their users. As a result, continuing liability insurance became unavailable (316). Although the company

had won most of the cases that went to trial, the costs of defending against the lawsuits were so high that Searle decided for financial reasons to stop marketing IUDs. As of March 1988 the company had won 14 of the 17 cases brought to court (457).

Why have there been so many lawsuits in the US over IUDs? This litigation is part of a larger US crisis in liability and liability insurance that is affecting many products and services in the health field as well as in other areas (3, 111, 292). In the last decade the number of lawsuits claiming that a product has caused harm (product liability lawsuits) and the number of malpractice suits against physicians has increased sharply (124, 403). For this and other economic reasons, it has become more difficult and expensive for pharmaceutical companies and other institutions to obtain insurance (76, 111, 299, 338, 403). (GynoPharma, the company that will market the TCu-380A in the US, has obtained insurance, however.)

IUD manufacturers are particularly subject to lawsuits because of the Dalkon Shield. The Dalkon Shield IUD was sold in the early 1970s but is no longer on the market. It was linked to spontaneous septic abortions and pelvic inflammatory disease (46). The extent of health risks with the Dalkon Shield was apparently due to its particular design (372). Although other IUDs have been associated with much lower health risks (see p. 12), some have been subject to many lawsuits along with the Dalkon Shield.

### Public Health Organizations Reaffirm Support for IUDs

When the US pharmaceutical companies stopped selling IUDs, national and international health and family planning organizations protested. All reaffirmed their support for IUDs and recommended that they be made widely available (2, 6, 8, 159, 161, 274). A WHO Scientific Group, convened in 1986 to review the safety of IUDs, concluded, "The use of IUDs in both developed and developing countries should continue to be supported as a reliable and safe method of reversible fertility regulation" (437). All donor agencies continue to provide IUDs on request from governments and private voluntary family planning agencies (see p. 20).

Despite these endorsements, the US situation may have been misunderstood. For example, in an informal 1986 survey, 9 of 29 African family planning directors said that they thought most IUDs were no longer sold in the US because they were declared unsafe (97). The directors did not realize that the manufacturers' decisions were primarily financial. Introduction of the TCu-380A in the US should help to correct these misunderstandings.

## IUD PERFORMANCE

IUDs can be classified as either:

- unmedicated, or inert, or
- medicated—that is, copper or hormone-releasing.

Of the eight types of IUDs now widely used, two are unmedicated and six are copper.

The **Lippes Loop**, made of polyethylene, is the most widely used unmedicated IUD outside China. The other major types of unmedicated IUDs are the flexible **stainless steel rings** (either round or in the shape of the uterine cavity and made with a single or double coil). These rings are widely used in China but are not used elsewhere.

Medicated IUDs have either copper or hormones added to a plastic frame. The first generation of copper IUDs carried copper wire with a surface area of 200 to 250 $mm^2$. Two of these—the **TCu-200** and the **Multiload-250** (**MLCu-250**)—are still widely available. The second generation of copper IUDs introduced several innovations—more copper wire, copper sleeves, and/or a silver core to the copper wire (denoted by Ag in the IUD name). These changes increase effectiveness and extend effective lifespan (see box, p. 6). The major second-generation IUDs are the **TCu-380A**, **TCu-220C**, **Nova T**, and **Multiload-375** (**MLCu-375**).

Hormone-releasing IUDs constantly release small amounts of steroid hormone into the uterus. The only hormone-releasing device currently marketed is the **Progestasert**, containing 38 mg progesterone released at a rate of 65 µg per day for one year. A longer-lasting levonorgestrel-releasing IUD, the **LNG-20**, developed and widely tested by the Population Council, is not yet available (see box, p. 22).

**For the right women, the current generation of IUDs offer a highly effective, convenient, and safe way to avoid unwanted pregnancy. Here, in Bangladesh a family planning worker and her client talk about the TCu-380A IUD.**
(Photo by S.J. Staniski)

### Comparing IUDs

None of these IUDs is consistently superior to others in terms of effectiveness, side effects, expulsion, and continuation. In general, however, second-generation copper IUDs are much more effective and have fewer side effects than unmedicated IUDs.

Pregnancy and complication rates, even with the same IUD, vary in

## Table 1. Performance of Copper IUDs, Selected Randomized Multicenter Comparative Trials, 1975–1987

| Author & Date (Ref. No.) | Place | Life-Table Method[a] | IUDs Studied | No. of Women | Rate per 100 Women of Removal for: Accidental Pregnancy | Expulsion | Bleeding /Pain | Infection | Other Medical | Continuation Rate |
|---|---|---|---|---|---|---|---|---|---|---|
| **12-Month Rates** | | | | | | | | | | |
| **Cole et al. 1985** (73) | Costa Rica, Egypt, Panama, Yugoslavia | Noncompeting | TCu-380Ag | 737 | 0.3 | 3.3 | 3.6 | —0.4— | | 90.9 |
| | | | MLCu-375 | 740 | 0.8 | 4.1 | 3.6 | —1.1— | | 88.7 |
| **Kozuh et al. 1986** (200) | Yugoslavia | Noncompeting | Nova T | 410 | 1.0 | 2.0 | 6.0 | 0.2 | 0.2 | 89.4 |
| | | | TCu-200Ag | 409 | 3.0 | 0.7 | 3.8 | 0.3 | 0.3 | 90.5 |
| **Luukkainen et al. 1983** (226) | Denmark, Finland, Sweden | Noncompeting | Nova T | 918 | 0.8 | 5.8 | 11.9 | 2.5 | 0.9 | 76.1 |
| | | | TCu-200Ag | 947 | 2.1 | 4.6 | 12.2 | 2.0 | 1.5 | 76.7 |
| **Sivin & Stern 1979** (332) | Canada, US | Competing | TCu-200 | 1,014 | 2.1 | 7.1 | 10.3 | —3.6— | | 72.5 |
| | | | TCu-220C | 1,097 | 0.9 | 8.0 | 11.5 | —2.3— | | 73.5 |
| | | | TCu-200 | 1,851 | 3.1 | 7.1 | 11.5 | —2.8— | | 70.8 |
| | | | TCu-380A | 1,679 | 1.0* | 7.1 | 14.2 | —3.0— | | 69.7 |
| **Sivin et al. 1987**[b] (335) | Brazil, Chile, Dominican Republic, Egypt, Singapore, US | Competing | TCu-380Ag | 1,120 | 0.3 | 5.5 | 7.0[c] | 0.9 | 2.8 | 79.8 |
| | | | LNG-20 | 1,124 | 0.2 | 6.0 | 10.9[c] | 1.0 | 3.4 | 73.5* |
| **Sung et al. 1984** (363) | People's Republic of China | Competing | TCu-380Ag | 892[d] | 0.1 | 4.3[g] | 6.8 | —0.3— | | 88.4 |
| | | | TCu-220C | 887[e] | 0.3 | 1.6* | 3.3[h]* | —0.0— | | 94.5* |
| | | | Mahua Ring | 983[f] | 3.0* | 6.3 | 4.3 | —0.3— | | 86.1 |
| **Thiery et al. 1980** (381) | Belgium | Noncompeting | TCu-200 | 730 | 1.0 | 2.7 | 1.4 | 0.2 | NA | 93.1 |
| | | | MLCu-375 | 664 | 0.5 | 1.2 | 2.3 | 0.1 | NA | 94.4 |
| **Wilson 1986** (432) | New Zealand | Competing | Nova T | 509[i] | 1.7 | 3.6 | 9.8 | 2.1 | 2.2 | 77.2*[j] |
| | | | MLCu-375 | 475[i] | 1.5 | 2.2 | 6.2[k] | 1.2 | 0.7 | 80.4 |
| | | | MLCu-250Ag | 457[i] | 0.3* | 1.6 | 7.2 | 0.5 | 1.2 | 82.7 |
| **WHO 1982** (444) | Egypt, Hungary, India, Philippines, Thailand, UK, US, USSR, West Germany | Noncompeting | TCu-220C | 984 | 0.5* | 3.7* | 2.2*[l] | 0.5 | 1.2 | 76.3 |
| | | | Lippes Loop D | 992 | 1.9 | 7.8 | 4.5[l] | 0.1 | 0.5 | 68.8*[m] |
| | | | Cu-7 | 994 | 1.9 | 6.3 | 3.6[l] | 0.1 | 1.3 | 70.6 |
| **24-Month Rates** | | | | | | | | | | |
| **Goh et al. 1985** (121) | Indonesia, Malaysia, Singapore | Competing | MLCu-250 | 580 | 2.5 | 2.1 | 6.1 | —4.3— | | 74.0 |
| | | | TCu-220C | 569 | 1.7 | 3.8 | 6.0 | —3.5— | | 73.0 |
| | | | Cu-7 | 576 | 4.9 | 8.5* | 5.1 | —2.9— | | 69.0 |
| **Kozuh et al. 1986** (200) | Yugoslavia | Noncompeting | Nova T | 410 | 1.7* | 3.0 | 9.2 | 0.6 | 0.5 | 81.2 |
| | | | TCu-200 | 409 | 5.5 | 1.4 | 6.3 | 0.5 | 0.6 | 80.2 |
| **Luukkainen et al. 1983** (226) | Denmark, Finland, Sweden | Noncompeting | Nova T | 918 | 1.8* | 7.8 | 19.1 | 3.3 | 2.1 | 51.6 |
| | | | TCu-200Ag | 947 | 4.8 | 6.0 | 16.4 | 2.7 | 3.2 | 64.7 |
| **Saure et al. 1985** (314) | Finland | Competing | Fincoid-350 | 449 | 1.3 | 9.2 | 13.2 | 2.3 | 2.7 | 65.1 |
| | | | MLCu-375 | 432 | 0.9 | 10.2[n] | 12.3 | 2.2 | 0.6 | 65.6 |
| | | | Nova T | 452 | 2.3 | 4.7 | 10.8 | 1.7 | 1.5 | 72.5 |
| **Sivin & Stern 1979** (332) | Canada, US | Competing | TCu-200 | 1,014 | 5.0 | 9.0 | 16.1 | —5.0— | | 55.9 |
| | | | TCu-220C | 1,097 | 1.8* | 9.8 | 17.1 | —4.0— | | 59.7 |
| | | | TCu-200 | 1,851 | 5.6 | 8.3 | 18.9* | —4.3— | | 50.0 |
| | | | TCu-380A | 1,679 | 1.0* | 9.5 | 23.7 | —4.7— | | 50.1 |
| **Sivin et al. 1987**[b] (335) | Brazil, Chile, Dominican Republic, Egypt, Singapore, US | Competing | TCu-380Ag | 1,120 | 0.7 | 6.1 | 11.5[c] | 1.5 | 4.6 | 67.5 |
| | | | LNG-20 | 1,124 | 0.2 | 7.3 | 17.0[c] | 1.3 | 5.6 | 59.4* |
| **Sung et al. 1985** (364) | People's Republic of China | Competing | TCu-380Ag | 892[d] | 0.6 | 5.3 | 8.9 | —0.7— | | 83.9 |
| | | | TCu-220C | 887[e] | 1.8 | 2.1* | 7.1 | —0.0— | | 88.4* |
| | | | Mahua Ring | 983[f] | 6.0* | 6.9 | 7.8 | —0.8— | | 78.3 |
| **Thiery et al. 1980** (381) | Belgium | Competing | TCu-200 | 730 | 1.2 | 3.1 | 1.9 | 0.2 | NA | 90.0 |
| | | | MLCu-250 | 664 | 1.1 | 1.2 | 3.8 | 0.1 | NA | 89.5 |
| **WHO 1982** (444) | Egypt, Hungary, India, Philippines, Thailand, UK, US, USSR, West Germany | Noncompeting | TCu-220C | 984 | 1.7* | 6.1*[p] | 3.9*[l] | 0.5 | 2.9 | 60.3* |
| | | | Lippes Loop D | 992 | 3.7 | 10.0 | 7.9[l] | 0.3 | 1.4 | 54.8 |
| | | | Cu-7 | 994 | 3.6 | 7.9 | 6.5[l] | 0.1 | 3.7 | 55.5 |

**Table 1 Continued**

| Author & Date (Ref. No.) | Place | Life-Table Method[a] | IUDs Studied | No. of Women | Rate per 100 Women of Removal for: Accidental Pregnancy | Expulsion | Bleeding /Pain | Infection | Other Medical | Continuation Rate |
|---|---|---|---|---|---|---|---|---|---|---|
| **36-Month Rates** | | | | | | | | | | |
| **Luukkainen et al. 1983** (226) | Denmark, Finland, Sweden | Noncompeting | Nova T | 918 | 2.7* | 9.8 | 25.0 | 4.6 | 2.8 | 48.2 |
| | | | TCu-200Ag | 947 | 6.5 | 6.8* | 23.2 | 4.9 | 4.4 | 51.1 |
| **WHO 1988** (307) | 13 centers worldwide | Noncompeting | TCu-380A | 1,396 | 1.0* | 6.9 | 12.5 | 0.1 | 1.7 | 63.7 |
| | | | TCu-220C | 1,396 | 3.3 | 7.7 | 11.6 | 0.3 | 0.9 | 62.5 |
| | 19 centers worldwide | Noncompeting | TCu-220C | 1,881 | 4.4* | 6.6 | 11.4 | 0.2 | 1.4 | 62.5 |
| | | | Nova T | 1,847 | 6.4 | 6.0 | 10.5 | 0.3 | 1.6 | 60.2 |
| **48-Month Rates** | | | | | | | | | | |
| **Luukkainen et al. 1983** (226) | Denmark, Finland, Sweden | Noncompeting | Nova T | 918 | 2.9* | 11.0 | 30.0 | 5.9 | 3.4* | 39.8 |
| | | | TCu-200Ag | 947 | 7.1 | 9.0 | 27.2 | 6.0 | 7.9 | 40.5 |
| **WHO 1988** (307) | 13 centers worldwide | Noncompeting | TCu-380A | 1,396 | 1.1* | 7.7 | 14.4 | 0.1 | 2.3 | 56.6 |
| | | | TCu-220C | 1,396 | 3.9 | 8.4 | 14.1 | 0.4 | 1.4 | 54.3 |
| | 19 centers worldwide | Noncompeting | Nova T | 1,847 | 8.4 | 6.2 | 11.6 | 0.4 | 1.7 | 54.2 |
| | | | TCu-220C | 1,881 | 5.1* | 7.0 | 13.1 | 0.2 | 2.1 | 57.5 |
| **60-Month Rates** | | | | | | | | | | |
| **Luukkainen et al.1983** (226) | Denmark, Finland, Sweden | Noncompeting | Nova T | 918 | 3.4* | 12.5 | 34.7 | 7.2 | 5.1* | 33.2 |
| | | | TCu-200Ag | 947 | 8.7 | 9.9 | 29.8 | 6.5 | 8.3 | 36.0 |
| **WHO 1988** (307) | 13 centers worldwide | Noncompeting | TCu-380A | 1,396 | 1.4* | 8.0 | 17.3 | 0.1 | 2.4 | 50.5 |
| | | | TCu-220C | 1,396 | 3.9 | 9.1 | 16.4 | 0.6 | 1.5 | 49.0 |
| | 19 centers worldwide | Noncompeting | Nova T | 1,847 | 10.0 | 6.2 | 13.4 | 0.4 | 2.0 | 50.6 |
| | | | TCu-220C | 1,881 | 5.4* | 7.6 | 14.5 | 0.2 | 2.8 | 54.5 |
| **72-Month Rates** | | | | | | | | | | |
| **WHO 1988** (307) | 13 centers worldwide | Noncompeting | TCu-380A | 1,396 | 1.4* | 8.0 | 19.2 | 0.1 | 2.4 | 47.3 |
| | | | TCu-220C | 1,396 | 4.5 | 9.9 | 17.1 | 0.6 | 1.7 | 45.1 |

*Reported as statistically significant difference. (In studies comparing three IUDs, the asterisked rate is significantly different from both other rates except where noted.)

[a]Life-table techniques are used to calculate rates of removal and continuation taking into account the varying lengths of time that women remain in a study. Noncompeting life-table rates, also known as gross cumulative rates or, by the World Health Organization, as cumulative net probability rates, are the discontinuation rates for a single event among current users. That is, when the rate is calculated, discontinuations for other reasons are taken into account. Competing rates, also called net cumulative rates or cumulative crude rates, are cumulative discontinuation rates for an event among all users without adjusting for other events. Noncompeting rates are most appropriate for comparing event rates among different devices. Competing rates provide an estimate of overall IUD performance, showing the relative importance of different reasons for discontinuation. Competing rates may be unreliable when comparing specific reasons for discontinuation between devices.

[b]13-month rates

[c]Includes removal for amenorrhea: at 13 months, 0.1 for the TCu-380Ag and 4.9 for the LNG-20; at 25 months, 0.2 for the TCu-380Ag and 8.4 for the LNG-20

[d]27 percent postabortion insertions

[e]36 percent postabortion insertions

[f]25 percent postabortion insertions

[g]More than half of TCu-380Ag expulsions occurred at one of the five centers.

[h]TCu-220C and TCu-380Ag significantly different

[i]Number of women finishing 12 months

[j]MLCu-250Ag and Nova T significantly different

[k]MLCu-375 and Nova T significantly different

[l]Removals for bleeding only

[m]Lippes Loop and TCu-220C significantly different

[n]Partial expulsion rates for MLCu-375 and Nova T are significantly different. Complete expulsion rates are not.

[o]25-month rates

[p]TCu-220C and Lippes Loop significantly different

different clinics and studies. This is partly because the women may be dissimilar—in age, parity, and other factors that influence IUD performance. Also, the quality of care may vary. Thus randomized multicenter studies usually are the most reliable way to evaluate and compare IUD performance. Results of such studies are presented in Table 1.

While efforts to design better IUDs continue (see box, p. 22), the quality of care that IUD users receive may make more difference to IUD performance than the design of a specific IUD. The health care provider's training and experience, particularly with insertion technique, are especially important.

It is customary to evaluate IUDs in terms of contraceptive effectiveness, continuation, and rates of removal due to side effects and complications—bleeding and pain, perforation, expulsion, and infection. All are measured in life-table rates—the number of pregnancies or removals per 100 or 1,000 women after a specified length of IUD use.

### Effectiveness

The IUD is one of the most effective methods of contraception. With most devices, pregnancy rates range from one to three per 100 women per year. Four of the newer copper IUDs—the TCu-380A, TCu-380Ag, TCu-220C, and MLCu-375—are slightly more effective than others. Pregnancy rates for these devices are less than one per 100 women per year (331) (see Table 1). In a WHO international study, after six years of use

*With the new IUDs, pregnancy rates are less than one per 100 women per year.*

the cumulative pregnancy rate with the TCu-380A is 1.4 per 100 women, and with the TCu-220C, 4.5 per 100 women (307). This is the longest major international study.

Pregnancy rates for earlier devices—the TCu-200, the Cu-7, and the Lippes Loop—are about 2 per 100 women per year (331) (see Table 1). The Chinese ring is less effective, with pregnancy rates of 3 per 100 women at one year and 6 per 100 at two years (363, 364).

Like most other reversible contraceptives, the IUD does not perform as well in general use as in clinical trials (387). Still, in practice it remains one of the most effective reversible contraceptive methods. In fact, in developing countries IUDs are often more effective than oral contraceptives. According to World Fertility Survey data from five Latin American countries in the 1970s, for example, the pregnancy rate was 5 per 100 IUD users per year, 8 per 100 oral contraceptive users, and 18 per 100 condom users (122). A 1980 Philippine survey also reported markedly lower pregnancy rates among IUD users than among oral contraceptive users (204).

### Continuation

Women use IUDs longer than most other reversible contraceptive methods. According to large multicenter trials in developing countries, about 70 to more than 90 per 100 women are still using their IUDs one year after insertion (see Table 1). In a WHO study, six years after insertion 47 per 100 women were still using the TCu-380A (307). IUD continuation rates in clinical trials are as high or higher than for Norplant implants (470, 472) and higher than for oral contraceptives, condoms, or diaphragms (204, 437, 473). Even outside clinical trials, IUD continuation rates are high. The 1980 study in the Philippines

## *Lifespan of Copper IUDs*

Clinical trials show that all of the widely used copper IUDs are effective for at least five years (21, 225, 226, 307, 380, 383, 405, 451, 453). Researchers think that the second-generation copper IUDs are probably effective for much longer (279, 411). Copper IUDs are currently approved for only three to five years, however (see table at right). Regulatory approvals are generally based on effectiveness demonstrated in clinical trials but often lag behind the latest findings.

The few long-term randomized clinical trials of copper IUDs report low cumulative pregnancy rates for the second-generation copper IUDs—after six years, 1.4 per 100 women with the TCu-380A and 4.5 with the TCu-220C, and, after five years, 3.4 with the Nova T (226, 307) (see Table 1). By comparison, nonrandomized trials of the TCu-200, a first-generation copper IUD with less copper, report higher 5-year pregnancy rates—from 7 to 12 per 100 women (331, 451, 453). Large nonrandomized trials of Multiload IUDs have found low 4-year pregnancy rates—2.5 per 100 women for the MLCu-375 and 1.2 per 100 women for the MLCu-250 (380, 383).

With the TCu-380A, Nova T, TCu-220C, MLCu-250, MLCu-375, and, according to most studies, the TCu-200, annual pregnancy rates do not increase over a 4- or 5-year period. In fact, annual pregnancy rates in the fourth or fifth years of IUD use are lower than in the first year (21, 226, 254, 331, 333, 380, 405). This is largely because women using IUDs for long periods tend to be older and thus less fertile than short-term users (437). Also, women whose IUDs are improperly inserted, expelled, or perforate the uterus are most likely to become pregnant early in the study. Declining pregnancy rates over long periods are seen also in women using noncopper devices such as the Lippes Loop (385).

Researchers estimate that copper IUDs may be effective for up to three times longer than yet demonstrated in clinical trials (89, 199, 206, 411, 452)—for 10 years or perhaps even more for the TCu-380, TCu-380Ag, TCu-220C, and Nova T (249, 279). Such estimates are imprecise, however. They are based on projections about rates of copper loss from IUDs. These rates are variable and difficult to ascertain (50, 252).

Researchers continue to study women using second-generation copper IUDs for increasing lengths of time. If pregnancy rates remain low, as expected, and if other complication rates are acceptable, the approved lifespans of some copper IUDs may be extended. Less frequent replacement would reduce the risks of pelvic inflammatory disease, perforation, and other complications that mainly occur soon after insertion. Also, less frequent insertion would cost less and be more convenient.

**Copper IUDs: Demonstrated Lifespans and Regulatory Approvals in Selected Countries**

| Type | Years of Lifespan Demonstrated in Clinical Trials (Ref. No.) | | Regulatory Agency Approval | |
|---|---|---|---|---|
| | | | Country | Years Permitted |
| **TCu-380A** | 6 | (307) | US & UK | 4 |
| | | | Various European | 5 |
| **TCu-380Ag** | 5 | (330) | Finland | 5 |
| **TCu-200** | 6 | (453) | US* | 4 |
| | | | Various European | 3 |
| **TCu-220C** | 10 | (379) | Mexico | 3 |
| **Nova T** | 5 | (226, 307) | Various European | 5 |
| **MLCu-250** | 8 | (21) | Various European | 3 |
| **MLCu-375** | 5 | (380) | Various European | 5 |

*For TCu-200B

estimated one-year continuation rates of 70 percent among IUD users compared with 42 percent among oral contraceptive users and 10 percent among condom users (204). Similarly, statistics from the Indonesian national family planning program showed that 65 to 75 percent of IUD users were still using their method after three years compared with 30 to 40 percent of oral contraceptive users (98).

### Bleeding and Pain

Increased menstrual bleeding, often with pain, is the most common problem of IUD use and the most common medical reason for removing IUDs. In clinical trials roughly 4 to 15 percent of women stop using IUDs for this reason within a year after insertion. Percentages are usually higher for the Lippes Loops and other unmedicated devices than for copper IUDs.

Older women and women with children generally have lower rates of removal due to bleeding and pain (332, 463). The kind of counseling and support women receive and their attitudes toward using IUDs also influence rates of discontinuation due to bleeding and pain (27). Women who want no more children, for example, may be more tolerant of heavy bleeding and less likely to discontinue than younger women who plan to have more children.

Unmedicated and copper IUDs increase the volume of menstrual bleeding per cycle, probably because the IUD disturbs the blood vessels or alters the normal blood clotting mechanism in the lining of the uterus (341, 437). With unmedicated devices, blood flow increases on average by 50 to 100 percent above preinsertion levels (10, 132, 135, 167, 437); with copper IUDs, 20 to 50 percent (115, 135, 167, 207, 212, 229). With the Lippes Loop and TCu-220C, among others, these changes persist. With the TCu-200 and the Cu-7, blood loss gradually diminishes to preinsertion levels over the period from 12 to 24 months (10, 115, 437).

Unlike other IUDs, progestin-releasing devices decrease menstrual blood flow—by as much as 40 percent (131, 222, 223, 258, 465). The Progestasert, however, may increase the number of days of light bleeding and spotting, and the LNG-20 can stop menstruation (amenorrhea) (223, 258, 308, 335).

With all IUDs, abnormal bleeding and pain may be due, not to the IUD itself, but to pelvic inflammatory disease (PID), ectopic pregnancy, or other conditions. Therefore the health care provider should consider all conditions that might cause bleeding and pain.

**Risk of anemia**. An estimated 40 percent of nonpregnant women in developing countries are anemic (460). Many more have marginal iron levels (10). Thus increased bleeding with copper and unmedicated IUDs can be a cause for concern.

Whether IUDs increase the risk of anemia is uncertain, however. Some one- and two-year studies of copper and unmedicated IUDs show significant declines in serum ferritin, which measures early stages of iron depletion, and in hemoglobin, which measures only later stages (10, 115, 117, 134, 147, 167, 188). Others find no changes (212, 271, 284, 298, 320). The few long-term studies done have found little increase in anemia (329, 378, 437). In a study carried out in several developing countries and the US, 24 percent of women were anemic when they began using the TCu-380A. Four years later 25.4 percent were anemic (329). In the US and Finland studies report lower serum ferritin levels in long-term IUD users than in nonusers, but no cases of clinical anemia were seen (250, 378). In developing countries protection against repeated pregnancies—a major cause of iron depletion and anemia—may offset the increased menstrual bleeding with IUDs (437).

Hormone-releasing IUDs, by reducing menstrual bleeding, may actually protect against anemia. In a multicenter trial 21 percent of the women were anemic when they began using the LNG-20. After four years of use only 6 percent were anemic (329, 335).

### Perforation

Perforation of the uterus occurs when the IUD, the inserter tube, the sound, or another gynecological instrument pierces the uterine muscle wall. Most perforations apparently occur during insertion and involve the uterine fundus (top of the

## New Findings on How IUDs Prevent Pregnancy

Recent research is shedding new light on how IUDs prevent pregnancy. For years some people speculated that biochemical changes in the uterus caused by an IUD either destroyed the fertilized ovum or prevented implantation. New studies, however, suggest that IUDs act earlier in the reproductive process and actually prevent sperm from fertilizing ova (437).

In the first study of its kind, researchers in Chile recovered ova from 14 women using various IUDs and 20 women not using contraception. All of the women had recently had sexual intercourse around the time of ovulation. None of the ova recovered from IUD users showed clear signs of fertilization and normal embryonic development. In contrast, half of the ova recovered from nonusers did (260). These results provide the clearest evidence to date that IUDs generally work by preventing fertilization.

Studies using assays for human chorionic gonadotropin (hCG), a hormone secreted by cells surrounding the fertilized ovum, also suggest that IUDs generally prevent fertilization (317, 416, 427). These assays can detect fertilization within 7 to 10 days, well before implantation of a fertilized ovum is complete (106, 198, 437). Two studies of women using mainly copper IUDs have found hCG assays indicating fertilization in less than one percent of menstrual cycles (317, 427).

IUDs affect ova and sperm in various ways. They stimulate a pronounced inflammatory reaction, or foreign-body response, in the uterus. The concentration of various types of white blood cells, prostaglandins, and enzymes in uterine and tubal fluids increases markedly (174, 243, 264, 312, 322, 437), especially with copper IUDs (235). These changes may interfere with transport of sperm in the genital tract and may damage sperm and ova so that fertilization is impossible (260, 437). In most studies fewer sperm are found in the fallopian tubes, where fertilization is thought to take place, in IUD users than in nonusers (12, 193, 312, 386). Various types of white blood cells probably consume many sperm in the uterus (312). Other sperm may be damaged so that they cannot move into the fallopian tubes (260).

uterus). In large clinical trials perforation has been rare—no more than 1.2 per 1,000 insertions (73, 90, 200, 314, 332, 364, 437, 444). Perforations may go unnoticed at the time of insertion, however (42). Perforations may be partial, with just part of the IUD piercing the uterine wall or cervix, or complete, with the IUD passing through the uterine wall into the abdominal cavity. Also, over time IUDs may become embedded in the uterine wall without perforating it (42, 130, 340, 450).

In many cases a partial perforation of the uterine fundus heals quickly, and no treatment is required. Copper and hormone-releasing IUDs that have completely perforated the uterus should be removed as soon as possible, however. They can cause an inflammatory reaction and adhesions in the abdominal cavity (15, 437, 449). Some researchers think that unmedicated devices also should be removed (42, 183, 237, 449). The Medical Advisory Panel of the International Planned Parenthood Federation considers this necessary only if the woman has abdominal symptoms (164).

## What's in a Name?

Many of the early IUDs were named after their inventors—for example, the Ota and Grafenberg rings after T.A. Ota of Japan and Ernst Grafenberg of Germany and the Lippes Loop after Jack Lippes of the US. With more recently developed IUDs, manufacturers have conducted market research to come up with product names that suggest effectiveness, reliability,and other positive images. For example, GynoPharma, the company that will market the TCu-380A in the US, used focus-group discussions (small group discussions with a trained interviewer) and surveys to decide on the name ParaGard for the TCu-380A. Market research found that, to potential users, the name ParaGard suggests a modern and effective IUD. GynoPharma favors the name because "Para" suggests to doctors an IUD for parous women. Their research suggests that women usually accept their doctor's recommendation for an IUD (464).

In many parts of the world all kinds of IUDs are referred to as the loop or the coil or, in Spanish, *el espiral* or, in Arabic, *al lawlab* after the Lippes Loop and the Saf-T-Coil. There are also folk names for IUDs, such as, in Morocco, *al amalia saghirah*, meaning "the small operation" in contrast to "the big operation," which refers to tubal ligation (456).

Social marketing programs in many countries have given attention to naming contraceptives that are purchased directly by consumers. Names chosen for oral contraceptives—such as Gulaf, meaning rose, in Nepal and Maya, meaning affection, in Bangladesh—suggest femininity and caring. Names chosen for condoms—such as Panther in various countries and Raja, meaning king, in Bangladesh—suggest strength and masculinity (471). In contrast, little effort has been given to finding IUD names that would appeal to users. Although a good name cannot substitute for a good IUD, an appealing name coupled with a catchy logo and attractive packaging could help to promote a positive image of IUDs and heighten interest among potential users.

Careful insertion technique—including performing a pelvic examination and sounding the uterus—can prevent most perforations (see p. 9). Special care is needed when the uterus is retroverted (bent backward) (449).

### Expulsion

After IUD insertion, uterine contractions can push the device downward, causing partial or complete expulsion. Expulsion rates vary from less than one to more than 10 per 100 women in the first year of use (see Table 1). In general, unmedicated IUDs are expelled more often than copper devices. Among the copper devices, most studies have found that the Nova T and the Multiload IUDs are expelled least (73, 200, 381, 430). Most expulsions occur in the first year and especially the first three months after insertion (173, 314, 368, 385). Because undetected partial or complete expulsion can lead to unplanned pregnancy, IUD users should know how to check for the IUD strings to make sure that the device is still in place.

Several factors influence the chances of expulsion. Younger women and women who have never been pregnant or had children are more likely to expel their IUDs (333, 334, 340, 383, 437, 444). Correct insertion, with the IUD placed up to the fundus, is thought to reduce the chances of expulsion (60, 71) (see p. 9).

### Intrauterine Pregnancy

The IUD is a very effective contraceptive. If pregnancy does occur, however, potentially severe complications can result. Medical attention is always needed.

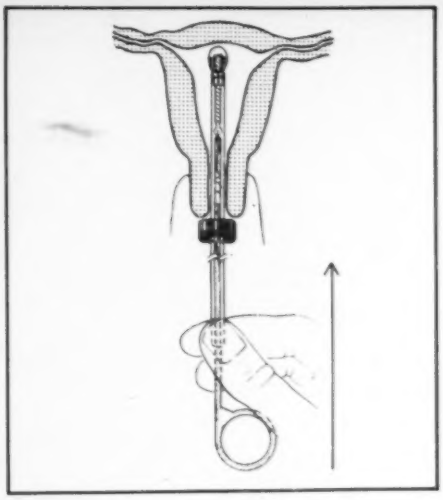
Spontaneous abortion is the most frequent complication of pregnancy with an IUD in place. Some 50 to 60 percent of uterine pregnancies spontaneously abort if the IUD is not removed (4, 195, 358, 371, 413, 463). This is $2^1/_2$ to 5 times more often than in other women (186, 413, 459). More than half of the spontaneous abortions in IUD users occur in the second trimester (215, 358). Septic (infected) second-trimester spontaneous abortion—a rare but life-threatening event—is 26 times more common in women whose IUDs are left in place than in women not using IUDs at the time of conception, according to a US study (109).

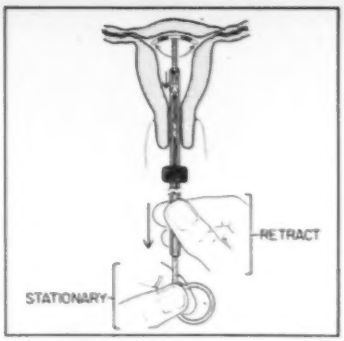
Because infection can occur in any pregnancy with an IUD in place, the IUD should be removed as soon as pregnancy is confirmed (1, 437). This markedly lowers the risk of spontaneous abortion and virtually eliminates the risk of septic abortion (4, 109, 195, 371). If IUD removal is difficult because the strings are not visible, WHO advises that the woman should be counseled about the risks of continuing her pregnancy (437).

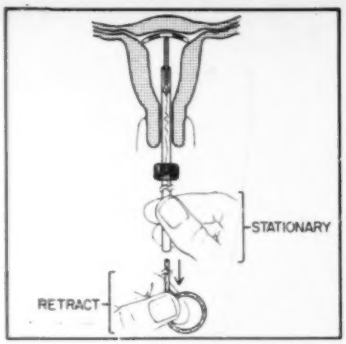
An IUD left in place during pregnancy also increases the risk of premature delivery, stillbirth, and low birth weight (413, 463). It does not increase the risk of other complications—birth defects, genetic abnormalities, or molar pregnancy (a uterine growth that mimics pregnancy) (152, 232, 276, 344, 371, 413).

### Ectopic Pregnancies

Mounting evidence indicates that IUDs do not increase the risk of ectopic pregnancy. A recent WHO multicenter study—the largest study to date—found that IUD users were 50 percent *less* likely to experience ectopic pregnancies than women using no contraception (442). A US case-control study also found a significant protective effect (261). IUDs provide less protection against ectopic pregnancy than oral contraceptives,






**The withdrawal method of IUD insertion is used for copper Ts, Multiloads, and the Progestasert. The tube containing the IUD is inserted up to the uterine fundus (left). The tube is withdrawn while the rod is held steady (center). Then the rod is withdrawn (right). Because insertion techniques vary among IUDs, the manufacturer's specific instructions should always be followed exactly. These diagrams from *The Copper T380 IUD: A Manual for Clinicians*, prepared by PIACT, show insertion of a TCu-380A (290).**

however (261, 442), and, according to the WHO study, barrier methods (442).

IUDs protect against intrauterine pregnancies better than against ectopic pregnancies. Thus, *when* an IUD user becomes pregnant, the pregnancy is more likely to be ectopic than a pregnancy in another woman (369, 424, 442, 463). In IUD users an estimated one in 30 pregnancies, or 3 to 4 percent, is ectopic. In the general population about one in 125 pregnancies, or 0.8 percent, is ectopic (39, 273, 332, 369).

Any pregnancy in an IUD user is uncommon, however. Thus ectopic pregnancy in an IUD user is rare. For most of the widely used IUDs, less than 1.5 ectopic pregnancies occur per 1,000 woman-years of IUD use (69, 73, 314, 327, 330, 335).

**Differences among devices**. Among inert and copper devices, ectopic pregnancy rates seem to reflect overall effectiveness. For example, two of the most effective IUDs, the TCu-380A and MLCu-375, have the lowest ectopic pregnancy rates—0.25 and 0 per 1,000 woman-years, respectively, according to a compilation of results from major trials (69, 73, 314, 330, 335). In contrast, the Progestasert has higher rates than other IUDs—4 to 5 per 1,000 woman-years (116, 327, 400). Very few ectopic pregnancies have been reported with the LNG-20 IUD (224, 330), in part because it sometimes suppresses ovulation (257).

While some questions about IUDs and ectopic pregnancy remain unanswered, the clinical implications are clear:

- Women using IUDs should be told about ectopic pregnancy. They should know the symptoms—abdominal pain, dark and scanty vaginal bleeding, intermenstrual bleeding, or amenorrhea—and to get medical care promptly.
- If an IUD user conceives or shows symptoms of ectopic pregnancy, health care providers should always look for ectopic pregnancy.
- An IUD is not the first choice for a woman at high risk of ectopic pregnancy—as indicated by previous ectopic pregnancy or pelvic inflammatory disease. Other methods provide more protection.

### Other Complications

There is no evidence that IUDs cause any type of cancer (148, 194, 280, 332, 436). Unlike oral contraceptives, however, IUDs do not protect against endometrial or ovarian cancer, and, unlike barrier methods, they do not protect against cervical cancer. Health care providers need to remember that abnormal bleeding in an IUD user is not always due to the device but may be a symptom of malignancy or other disease (45, 154). IUD users may be more likely to develop nonspecific vaginitis (often called bacterial vaginosis), according to two recent studies (455, 474), but more confirmation is needed. (For discussion of pelvic inflammatory disease, a more severe but uncommon complication, see pp. 12-15.)

Death from causes related to reproduction are rare among IUD users. WHO and US researchers have estimated about one to two deaths per 100,000 IUD users per year—from infection, ectopic pregnancy, or second-trimester septic abortion (262, 301, 384, 436). Mortality among women not practicing contraception is considerably higher because of the risks of childbearing. In developing countries maternal mortality rates range from 50 to 700 deaths per 100,000 live births, and in developed countries, from 3 to 30 (475).

## INSERTION

Proper IUD insertion reduces the risks of pregnancy and of all major side effects—expulsion, bleeding and pain, perforation, and infection. IUDs can be inserted safely at any time during the menstrual cycle as long as pregnancy is ruled out. Postpartum insertion also is safe and is convenient. High expulsion rates are a drawback, however.

### Insertion Technique

The objective of IUD insertion is to place the IUD correctly while minimizing the woman's discomfort and the risk of complications. Successful IUD insertion requires:

- **Explaining the procedure** to the client and responding to her questions and concerns. This helps the client relax, making insertion easier and less painful.
- **Careful technique** during all phases of insertion. This reduces the client's discomfort and reduces the chances of uterine perforation, cervical laceration, and other complications (57, 62, 63, 123).
- **Aseptic (sterile) technique** throughout the procedure including careful disinfection of all instruments (see box, p. 10). This minimizes the chances of pelvic inflammatory disease.

- **Careful bimanual pelvic examination and sounding of the uterus** to determine its depth and direction. This reduces the risk of perforating the uterus, which usually occurs because the sound or IUD is inserted too deeply or at the wrong angle (7, 63, 190, 395, 437).

- **IUD placement high in the uterus** (that is, at the fundus). This minimizes expulsions, accidental pregnancies, and possibly bleeding (71, 269, 332, 382).

IUD insertion is usually uncomplicated. While many women experience discomfort, less than 5 percent experience

## *Disinfecting Instruments for IUD Insertion*

Meticulous aseptic techniques are essential to minimize the risk of infection during IUD insertion. These techniques include handwashing with an antiseptic or, preferably, use of sterile gloves, cleaning the vagina and cervix with an antiseptic before IUD insertion, and proper cleaning and disinfection of instruments (283).

Disinfection of instruments and IUDs, if properly carried out, destroys most microorganisms including hepatitis B, herpes simplex type 2, and human papilloma virus (96). The standard high-level disinfection procedures, described here, also destroy human immunodeficiency virus (HIV), which causes AIDS (435). True sterilization—that is, destroying *all* microorganisms—for example, by autoclaving metal instruments—is desirable but not necessary (96, 191, 436).

Metal instruments, such as forceps and uterine sounds, should be disinfected by boiling or by soaking them in a high-level disinfectant such as glutaraldehyde or in alcohol or iodine solutions—sometimes called "cold sterilization" (see table at right). Low-level disinfectants such as benzalkonium chloride (for example, Zephiran) and cetrimide solutions (such as Savlon, which is a mixture of cetrimede and chlorhexidene) do not kill viruses and some other microorganisms and should not be used (96, 283).

Whichever disinfectant is used, instruments must be thoroughly cleaned beforehand. They should be scrubbed with a brush and soap or detergent to remove blood, mucus, and other organic soil that may trap microorganisms (281, 283, 435).

The health care provider must be sure that the IUDs themselves are disinfected before insertion. Copper IUDs are supplied in individual sterilized packages with a sterile inserter. If the package is damaged, the IUD and inserter may no longer be sterile, and it is best to discard them (36, 191, 213). If this is not feasible, IUDs and inserters can be disinfected by soaking in a high-level disinfectant (see table). Lippes Loops and their reusable inserters are usually supplied in bulk, unsterilized, and must always be disinfected before use. Copper and plastic IUDs should never be boiled or autoclaved because heat deforms them (436). The Lippes Loop reusable inserter can be boiled, however (191). If after disinfection an IUD is not used immediately, it can be disinfected again. This should not be done more than three times because the plastic may become brittle (165).

Disinfectants must be carefully prepared according to the manufacturer's instructions. Fresh solution should be prepared daily or more often, as needed (190, 436).

Instruments and IUDs should be carefully handled after disinfection so that they are not contaminated. Providers should touch them only with sterile gloves or sterile tools. Disinfected IUDs and instruments can be stored dry for a few days, wrapped in sterile cloth (281). Instruments soaked in disinfectants must be thoroughly washed in sterile (boiled or sterile bottled) water before use. Disinfectant solution left on instruments can irritate the client's skin or uterus (281, 435).

### Methods for Disinfecting Instruments and IUDs

**Copper IUDs and Inserters, Lippes Loops**

Soak for 30 minutes in aqueous iodine solution (1:2500)

**or**

Soak for 30 minutes in 70 percent alcohol (ethyl or isopropyl)

**or**

Soak for 30 minutes in activated glutaraldehyde (Cidex or Sporiciden) or, for complete sterilization, Cidex for 10 hours or Sporiciden for 6 3/4 hours

After any of these, wash IUDs and inserters thoroughly in sterile or boiled water.

**Reusable Lippes Loop Inserters**

Soak for 30 minutes in aqueous iodine solution (1:2500)

**or**

Soak for 30 minutes in 70 percent alcohol (ethyl or isopropyl)

**or**

Soak for 30 minutes in activated glutaraldehyde (or longer, as above)

**or**

Boil for 20 minutes in a container with a lid (longer at high altitudes)

After the first three methods, wash inserters thoroughly in sterile or boiled water.

**Metal Instruments, Rubber Gloves**

Soak for 30 minutes in activated glutaraldehyde (or overnight, as above). Wash instruments and gloves thoroughly in sterile or boiled water.

**or**

Boil for 20 minutes in a container with lid (longer at high altitudes). (Rubber gloves should not be boiled.)

**or**

Autoclave for 30 minutes at 120°C with 15 pounds of pressure.

Sources: Finishing Enterprises (461), IPPF (164), Kleinman (190, 191), PIACT (290), Porter (283), WHO (435)

moderate to severe pain. Vasovagal reactions—such as perspiring, vomiting, and brief fainting—and cervical laceration occur in one percent of women or less. These problems are generally brief and rarely require immediate IUD removal. They do not affect later IUD performance (58). Women who have never given birth, have had few births, or have had a long interval since last giving birth are most likely to have these problems. Analgesics reduce discomfort (300).

Health care providers should never use force to insert an IUD. If the cervical canal is narrow, dilators or a laminaria tent may be used. (A laminaria tent is a small stick of a special type of seaweed that slowly expands as it absorbs moisture.) Cervical dilation does not increase the risk of later expulsion (55). Alternatively, the health worker may ask the client to return during her menstrual period, when insertion may be easier, or refer her to a more experienced provider. Insertion failures are rare—2 to 8 per 1,000 attempted insertions—and are usually due to excessive pain or to the larger size of inserter used with some types of IUDs (63).

Copper Ts and most other IUDs are appropriate for women with a normal uterine length—at least 6.5 cm. Smaller IUDs such as the MLCu-250 Short or Mini are recommended for a woman with a shorter uterus (104, 105, 290, 395, 411).

### Timing of Insertion

IUD insertion is safe and effective at any time during the menstrual cycle (70, 90, 375, 426, 437). An international study of about 12,000 women who had IUDs inserted at different times during their menstrual cycles and similar US studies found no advantage to the conventional practice of insertion during the first five days of the menstrual cycle (70, 91, 426). Thus, for a woman who is reasonably sure that she is not pregnant, the best time to insert an IUD is when she comes to the health center to request it (398).

### Postpartum Insertion

Postpartum IUD insertion within a few days after delivery is safe and convenient, with no increased risk of infection, perforation, or bleeding (19, 71, 160, 304, 305, 373, 375).

The serious disadvantage of postpartum insertion is the high expulsion rate. The IUD is easily expelled after childbirth because the uterus is contracting and the cervix is dilated (341). When the IUD is inserted immediately postpartum, expulsion rates at six months ranged from 31 to 41 per 100 in a WHO multicenter trial and from 12 to 22 in a Family Health International multicenter trial (71, 443). Insertion one to seven days after delivery results in even higher expulsion rates (71). Because insertion between two to three days after delivery through six to eight weeks postpartum has not been thoroughly studied, various groups advise special caution or even advise against inserting IUDs during this period (164, 398, 433).

IUDs modified to reduce expulsion after postpartum insertion have met with little success for the most part (60, 71, 361, 377, 410, 443). Research continues, however. Researchers are testing a modified TCu-380A. A piece of chromic catgut suture is looped around the top of the T. When the IUD is inserted, the catgut loop is pushed into the wall of the uterus with a needle inserter. Thus the IUD is anchored in place for three to five weeks until the catgut dissolves (367).

The health care provider's skill and experience are probably more important in reducing expulsions and other complications than the type of device used (60, 361, 377, 382). A large international study of immediate postpartum insertions found that expulsion rates at three months were almost twice as high for insertions performed during the first half of the study, when the practitioners were less experienced, than in the second half (60). Similarly, a Belgian study found that rates of expulsion, accidental pregnancy, and removal for pain, bleeding, and other medical reasons were lower when IUDs were inserted postpartum by more experienced practitioners (382).

*IUD insertion is safe and effective at any time during the menstrual cycle.*

**Insertion at cesarean section.** Nine studies in China and a small study in Belgium, examining IUD insertion through the abdominal incision immediately after cesarean delivery, found low expulsion rates (59, 64, 409, 437). Because most of this research has involved stainless steel Chinese IUDs, however, WHO recommends against routine postcesarean insertion of copper and hormone-releasing IUDs until more is known. When there has been prolonged labor or premature rupture of the membranes, postcesarean insertion should certainly be avoided because of the risk of infection (437).

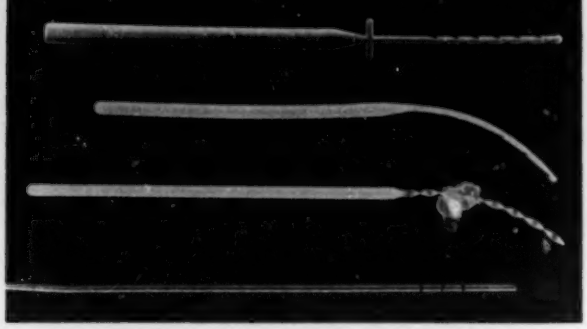
**Breastfeeding and IUDs.** The IUD is an ideal contraceptive method for lactating women (437) because it has no effect on the quantity or composition of breast milk (53, 72). There is concern, however, based on a few case reports and a case-control study involving 32 women, that insertion during lactation may involve a higher risk of uterine perforation (54, 144, 228). The results of the case-control study may be due to flaws in methodology, however (328). Another small study found that breastfeeding made no difference to the risk of perforation (56). Until conclusive research is done, special care—including especially careful sounding of the uterus to determine uterine depth—should be used when inserting an IUD in a lactating woman (398, 433).

### Postabortion Insertion

Conception can occur as early as 10 days after abortion. Therefore effective contraception is needed immediately (34). IUDs can safely be inserted after spontaneous or induced abortion except in women with pelvic infections (211, 436, 445). WHO studies show moderate expulsion rates following first-trimester abortions—ranging at two years from 5 to 9 per 100 women after induced abortion and from 10 to 14 after spontaneous abortion. With IUD insertion following a second-trimester abortion, rates of expulsion and of removal for pain and for other medical reasons are markedly higher (436, 445).

## REMOVAL

IUD removal is usually a routine and uncomplicated procedure. It can be done at any time during the menstrual cycle. To remove the IUD, the health worker pulls the strings slowly and gently with forceps. A tenaculum can be used to steady the cervix and align the endocervical canal and the vaginal and uterine cavities (357). If removal is not easy, the cervix can be dilated with metal dilators or a laminaria tent. Alternatively,



**IUD removal is usually uncomplicated. When the strings must be removed from the cervical canal, however, a narrow forceps can be used. Instruments to retrieve missing strings from the uterine cavity include (top to bottom) the Emmett IUD thread retriever, the Retrievette, the Mi-Mark Helix, and the experimental FHI string retriever.**

removal can be attempted again during menstruation, when the cervix is naturally softened (142, 190).

An international multicenter study found that less than 2 percent of attempted removals of standard IUDs proved difficult (61). One common reason for difficult IUD removal is that the IUD strings are "missing"—that is, they cannot be located in the vagina near the cervix (342). Usually, the strings have slipped up into the cervical canal, perhaps because they were cut too short at insertion. After ruling out pregnancy, the health care provider should use narrow forceps to probe the cervical canal and draw out the strings. A study in the UK found that missing strings could be retrieved this way in 50 percent of cases (202). If this fails, the strings may have retracted into the uterine cavity, or the IUD may have been expelled without the woman's knowledge. A sound can be used to check whether the IUD is in place. If it is, any of several special instruments can be used to draw out the strings (see photo above). Once the strings are retrieved, and if the woman wishes, it is often possible to leave the IUD in place if it has not been dislodged. Vacuum aspiration also can be used to find the strings. This usually dislodges the IUD, however (130). If the strings cannot be retrieved, IUDs can be removed from the uterus with forceps, curettes, or hooks. The health care provider must be very careful not to injure the uterus.

A less common reason for missing strings or difficult removal is that the IUD has partially or completely perforated the uterus or become embedded in the uterine wall. Perforation should be suspected particularly if the woman is experiencing abdominal or pelvic pain or irregular bleeding (449). If facilities are available, x-rays, hysterography (x-rays of the uterine cavity after instillation of a contrast medium), hysteroscopy (direct visualization of the uterine cavity with a fiberoptic instrument), or ultrasound imaging can be used to diagnose perforation and embedding (7, 15, 133, 237, 303, 449).

## INFECTION

Overall, women using IUDs are about twice as likely to develop pelvic inflammatory disease (PID) as women using no contraception, according to most studies (41, 78, 81, 209, 265, 421). This increased risk of PID is largely concentrated in the first few months after insertion and, thereafter, among women exposed to sexually transmitted diseases (STDs). For women in mutually faithful sexual relationships, IUDs pose little risk except in the first few months after insertion (208).

Pelvic inflammatory disease is a broad term for any infection ascending from the cervix into the uterus, fallopian tubes, and ovaries (422). PID is fairly common in developed countries. About one to two percent of all women of reproductive age develop PID every year (30, 421). In developing countries the incidence is unknown but may be higher in some areas (244, 302). STDs and postpartum and postabortion infections are major causes of PID (464).

The complications of PID often are severe. Even a single infection can permanently damage the lining of the fallopian tubes. This may partially or totally block one or both tubes, substantially increasing the chances of ectopic pregnancy and infertility (136, 369, 421, 424). With each episode of PID the chances of tubal blockage and infertility increase (422). A woman who has had PID is more likely to have chronic pelvic pain than other women and is more susceptible to repeated infections (422). All these complications are more likely if PID is not treated promptly and appropriately (see box, p. 13).

### PID and IUD Use

Epidemiologic research in the 1970s and early 1980s tended to overestimate the risk of pelvic infection from IUD use. These studies reported that IUD users were up to 10 times more likely to develop PID than other women (219). Several factors account for the initial overestimate, including:

- In most early studies the comparison group included women using oral contraceptives and barrier methods—methods that protect against PID.
- The risks for specific types of IUDs, particularly the Dalkon Shield, were not analyzed separately. The higher risk with the Dalkon Shield inflated overall risk estimates for all IUDs.
- Many studies did not take into account a number of important factors that affect the risk of PID—age, number of sexual partners, and history of PID (437).

Two large studies published in the 1980s have taken these earlier problems into account and find a lower risk. The US Women's Health Study found that IUD users were 1.6 times as likely to be hospitalized for PID as women using other methods or no method (41). A World Health Organization (WHO) study in 12 countries found that in developing countries IUD users with children were 2.3 times more likely to develop PID than women using no contraception. The relative risk for similar women in developed countries was 4.1 (446). IUD use also has been linked with a two- to threefold greater risk of primary tubal infertility, which is known to be caused by PID (see box, p. 14).

*For women in mutually faithful sexual relationships, IUDs pose little risk of infection except in the first few months.*

# Diagnosis and Treatment of Pelvic Inflammatory Disease

EARLY TREATMENT of pelvic inflammatory disease (PID) prevents severe tubal and abdominal infection. Also, early treatment reduces tubal damage and thus the chances of later infertility and/or ectopic pregnancy (178, 366).

Treatment for PID involves five steps:

1. Early diagnosis,
2. Antibiotic therapy,
3. Removal of the IUD, if present,
4. Frequent follow-up, and
5. Treatment of sexual partners (138).

Diagnosing PID can be difficult (169, 366, 421, 437). Some women may have very mild symptoms; others, none at all. Moreover, most signs and symptoms are not specific to PID. (For clinical signs of PID, see box, p. 23). They also may indicate ectopic pregnancy, appendicitis, or other abdominal illness (93, 421, 423). Laboratory tests can help diagnose PID. Strong indicators include: a positive cervical culture for gonorrhea or chlamydia; a white blood cell count of more than 10,000/mm$^3$ blood; and a gram stain of the endocervix positive for gram-negative intracellular diplococci (93, 138, 366).

Antibiotics effective against a wide range of bacteria are required to treat PID because many different organisms can cause the infection. Gonorrhea, chlamydia, and other sexually transmitted organisms often cause first episodes of PID. Subsequent infections usually involve bacteria normally found in the lower genital tract, such as *Escherichia coli, Proteus, Bacteroides, Clostridium,* and *Peptostreptococcus* (93, 128, 366, 422). Often, several different kinds of bacteria are involved in repeated episodes of PID.

Once the woman starts antibiotics, she should be followed carefully to ensure that the medicine is effective and to rule out other serious illness. Some clinicians recommend that a woman abstain from sexual intercourse until both she and her partner have finished the full course of antibiotics (93, 142). If the woman does not improve by 48 to 72 hours after starting antibiotics or if she develops a tubal abscess, she should be hospitalized for more intensive care (93, 366, 397, 420, 437). In severe cases surgery may be needed.

The World Health Organization and other authorities recommend that, if the woman is using an IUD, it should be removed 24 to 48 hours after she starts taking antibiotics (7, 93, 368, 397, 420, 437). Only one small study, however, has compared women whose IUDs were removed and women whose IUDs were left in place after diagnosis of PID. There was no difference between the two groups in the course of recovery (346).

Sexual partners of women with PID are likely to be infected with a sexually transmitted disease also. Even if asymptomatic, they should be tested and/or examined for clinical signs and symptoms of sexually transmitted diseases (see box, p. 23). In a recent British study 79 percent of the male partners of women with PID had nongonoccocal urethritis, but over three-quarters of these infected men had no symptoms (168). The woman and her partner(s) should be treated simultaneously with antibiotics effective against gonococcal and chlamydial infections (366, 397, 420).

## Recommended Antibiotic Regimens To Treat PID

### Out-Patient Treatment

**Probenecid**
One dose, 1.0 g by mouth
and
one dose of ONE of the following:

| | |
|---|---|
| **Cefoxitin** | 2.0 g IM |
| **Amoxicillin** | 3.0 g by mouth |
| **Ampicillin** | 3.5 g by mouth |
| **Penicillin G** | 4.8 million units IM at 2 sites |

**Followed by either**

**Doxycycline**
100 mg by mouth,
2 times/day, 10-14 days
and
**Metronidazole**
500 mg by mouth,
3 times/day, 14 days

**OR**

**Tetracycline**
500 mg by mouth,
4 times/day, 14 days

**OR***

**Ceftriaxone**
250 mg IM, one dose

**Followed by**

**Doxycycline**
100 mg by mouth,
2 times/day, 10-14 days

* The latter regimen is preferable where antibiotic-resistant strains of gonorrhea are prevalent.

### Hospital In-Patient Treatment

**Doxycycline**
100 mg, IV 2 times/day
and
**Cefoxitin**
2 grams IV, 4 times/day

Both for at least 4 days and at least 48 hours after patient improves

**Followed by**

**Doxycycline**
100 mg by mouth,
2 times/day, 10-14 days

**OR**

**Clindamycin**
900 mg IV, 3 times/day
mixed with
**Gentamicin**
(for women with normal kidney function)
2.0 mg/kg IV, then
1.5 mg/kg IV, 3 times/day

Both for at least 4 days and at least 48 hours after patient improves

**Followed by**

**Clindamycin**
450 mg by mouth,
4 times/day, 10-14 days

Note: These regimens are guidelines only. Other drugs may be used depending on availability and cost. Treatment of PID with penicillin, ampicillin, amoxicillin, or a cephalosporin alone may not be effective and is not recommended.
Sources: US CDC (397, 463), WHO (437)

**Population Reports**

Although IUD users are more likely to develop PID than nonusers, it is still an uncommon complication. A WHO study of multiparous women, mostly in developing countries, who were using copper IUDs reported a cumulative rate of removal for PID of less than one per 100 women after six years of use (307). Another multicenter study, involving women in Denmark, Finland, and Sweden, reported seven removals per 100 women after five years. Many of these women were young and unmarried and thus at higher risk for PID (226) (see Table 1).

### Factors Influencing the Risk of Infection

A number of factors clearly influence the risk of infection among IUD users:

**Insertion.** A woman is most likely to develop PID just after insertion (33, 41, 78, 209, 247, 307, 326, 356). In the Women's Health Study women using various IUDs, excluding the Dalkon Shield, were four times more likely to develop PID in the first month after insertion than women using no contraception. Two to four months after insertion, IUD users were 1.7 times more likely to develop PID. Thereafter IUD users were not at significantly higher risk of PID than women using no method (209). Women should therefore be especially alert to any symptoms of infection in the first few months after IUD insertion and should get prompt medical attention if they appear (see box, p. 25).

**Type of IUD.** The Dalkon Shield—which is no longer on the market—was as much as five times more likely to cause PID and two times more likely to cause tubal infertility than other IUDs (78, 81, 177, 209, 415). Moreover, with the Dalkon Shield, the high risk of developing PID persisted in long-term users (209).

It is not clear whether the risk of PID varies among other IUDs. Several studies show no difference in infection rates with the Lippes Loop, Cu-7, Saf-T-Coil, LNG-20, and Progestasert (177, 209, 335, 343, 422). In contrast, two studies on *infertility*,

## *Return of Fertility After IUD Use*

Most women who discontinue IUD use to become pregnant conceive as rapidly as nonusers. IUD use does, however, increase the risk of developing pelvic inflammatory disease (PID). Sometimes this leads to tubal infertility.

Two recent US case-control studies report that, overall, childless women with tubal infertility were two to three times more likely to have used IUDs than women having their first child. The risk of tubal infertility varied markedly with the type of IUD and with the number of the woman's sexual partners. Former copper IUD users had only slightly greater risk of tubal infertility than women who had never used IUDs. In contrast, former Dalkon Shield users had the highest relative risk (78, 81). Women who had had only one sexual partner in their lifetimes, regardless of the type of IUD used, had no increased risk of tubal infertility. Women who had had more than one partner, however, had three to four times higher risk, depending on the type of IUD. For women who already had one child, copper IUDs carried no increased risk of future infertility (78).

**Adjusted Relative Risks of Tubal Infertility Among Childless Women by Type of IUD and Number of Sexual Partners**

| | Number of Partners | |
|---|---|---|
| **Type of IUD** | **One** | **More than One** |
| **None** | 1.0 | 1.5* |
| **Copper** | 1.1 | 2.8* |
| **Other** | 0.7 | 4.2* |

*Statistically significant compared with nonusers with one partner

Adjusted for year of menarche, time between menarche and date women began trying to conceive, religion, education, and smoking

Source: Cramer et al. 1985 (78)

In contrast to these two case-control studies, most cohort studies, which have followed women who stopped using IUDs, have found no indication of impaired fertility. In 10 studies involving a total of about 3,800 women, from 72 to 96 percent of women *conceived* within a year after discontinuation (5, 9, 23, 84, 267, 291, 294, 332, 337, 431) and, in one large study, 51 percent *gave birth* within a year (and therefore a higher percentage presumably were pregnant) (414). These rates are in the same range as rates among women who have never used contraception (32, 323).

Most of these studies involved women who had no complications with IUD use (5, 9, 23, 84, 267, 291, 294, 332, 337) and who were unlikely to be exposed to sexually transmitted diseases—married women (9, 294, 337, 414) or women with children (9, 23, 84, 267, 414). Also, fertility rates among former IUD users were not directly compared with rates among women who had never used contraception. Therefore, these studies are not well-suited to evaluating whether IUD use might impair fertility in a small percentage of users. One cohort study did involve women who at some time had discontinued IUD use because of complications—pain, bleeding, or discharge. These women gave birth at only a slightly lower rate than groups of other women who had discontinued IUDs or other methods to become pregnant (414).

It is not clear whether longer IUD use is more likely to lead to infertility. Most cohort studies have found that women who used IUDs for long periods of time conceived about as rapidly as short-term users (9, 20, 23, 179, 291, 294, 337). One of the US case-control studies, however, found that the risk of infertility was slightly higher with longer use, once women who had used their IUDs for less than three months were excluded. Most of the women using their IUDs for less than three months had had their IUDs removed because of complications (78).

A recent case-control study suggests that current and former IUD users are no more likely than nonusers to develop tubal adhesions (fibrous bands of tissue), which can be caused by PID and are a major cause of tubal infertility. The study involved over 2,100 multiparous women undergoing voluntary sterilization. None reported using a Dalkon Shield, although not all could remember the type of IUD they had used. The results of this study fail to support other reports that IUD use increases the risk of PID and infertility (462).

rather than PID, reported lower risks of tubal blockage with copper IUDs than with unmedicated IUDs (78, 81) (see box, p. 14).

**Exposure to sexually transmitted diseases.** Much of the excess risk of PID in IUD users, apart from the first months after insertion, may be due to sexually transmitted diseases (208, 253, 437). Having had multiple partners—and, as a result, greater exposure to STDs—is thus a major PID risk for IUD users, as it is for all women regardless of contraceptive use. Women in mutually faithful sexual relationships face minimal risks, presumably because of less exposure to STDs (94, 208, 359, 360, 366, 423). If an IUD user's partner has more than one sexual partner, this also may increase her risk of PID (208, 356). An IUD user's risk of tubal infertility also may be associated with the number of sexual partners (78) (see box, p. 14).

**Age.** WHO multicenter studies found that, in the developing countries studied, risks of infection among IUD users were the same for younger and older women (446). In contrast, in developed countries PID in IUD users, as in nonusers, occurs more often among women under age 25 (24, 33, 41, 227, 360, 418, 421, 446). This may be at least in part because these younger women are less likely to be married or have mutually faithful sexual relationships (24, 33, 418, 446).

**Duration of IUD use.** In most studies the chances of ever developing PID remain unchanged or even decrease with duration of IUD use (41, 343, 415, 463). The risk of contracting very severe PID may increase with time, however (201, 356, 463). In the Women's Health Study women who had used the same IUD—regardless of type—for five or more years were about five times more likely than nonusers to develop severe PID requiring surgery. Women who had used the same IUD for less than five years were no more likely to have severe PID than nonusers. Long-term IUD users with more than one sexual partner in the year before hospitalization were at the highest risk of severe PID (356). The researchers speculate that most of these severe PID cases might have been caused by actinomyces (355). Actinomyces is an anaerobic bacterium that is usually harmless but may sometimes cause severe PID in long-term IUD users.

### Mechanisms of Infection

IUD use may increase the risk of pelvic infection in several ways (234). Organisms that normally live in the lower genital tract are introduced into the uterus during insertion (234), which occasionally leads to infection. Also, a sexually transmitted infection in the lower genital tract may be spread to the upper genital tract during insertion. In addition, nonbacterial inflammation of the fallopian tubes is more common in IUD users than nonusers (22, 74, 277, 339, 440). This inflammation may reduce resistance to disease-causing organisms (95, 339).

Some researchers suspect that cervical bacteria can move up the IUD string into the uterus (350, 352). Studies of IUDs without strings generally have not found lower rates of infection, however (see p. 18). One proposed explanation for the high rate of infection with the Dalkon Shield is that its multifilament string permitted bacteria to rise into the uterus more readily (296, 336, 372). All strings on currently available IUDs are monofilament.

### Prevention

Can pelvic infection among IUD users be prevented? Several approaches are being tried:

**Iyali sai farin ciki, ga Uwargida da wani ciki bayan da na karshe ya girma. Da zaran an cire wanna roba sai ciki.**

**"The happy family with the mother pregnant again after the last child is more grown up. Once the IUD is removed, the woman can become pregnant again." This illustration comes from a booklet for IUD users prepared by the Planned Parenthood Federation of Nigeria with assistance from Johns Hopkins Population Communication Services.**

- Better screening of clients,
- Prophylactic antibiotics at insertion,
- Better disinfection and insertion techniques, and
- IUDs without strings or with strings coated in disinfectant.

Identifying the right clients for IUDs is probably the most important way to reduce pelvic infections. Because PID is linked to sexually transmitted diseases, the best candidate for an IUD is a woman living in a stable, mutually faithful sexual relationship (127, 442, 437).

Administering broad-spectrum antibiotics just before IUD insertion may reduce pelvic infection in the first months of use. At the Kenyatta National Hospital, University of Nairobi, in Kenya, about 1,800 women received either a 200 mg oral dose of doxycycline or a placebo one hour before IUD insertion. According to preliminary analysis, in the six weeks after insertion the women receiving antibiotics had a 31 percent lower incidence of PID. The number of women who developed PID was too small, however, to draw firm conclusions. Also, additional studies are needed to evaluate the best dose and duration of prophylactic antibiotics (326). A similar study is underway at the University College Hospital in Ibadan, Nigeria (100). The cost of the antibiotic is fairly low—$.22 (US) per

**(Text continues on page 18.)**

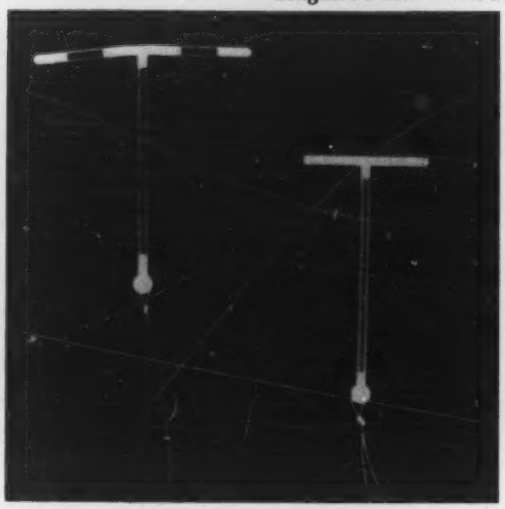
### TCu-380A, TCu-380Ag, and TCu-380 Slimline (TCu-380S)

**Description:** Polyethylene with barium sulfate added for visibility on x-rays. 314 $mm^2$ copper wire on vertical stem; two 33 $mm^2$ solid copper sleeves on each transverse arm. The wire in the 380Ag has a silver core. On the 380S the copper sleeves are placed at the ends of the arms and recessed into the plastic.

**Developers:** Population Council (US) and Ortho Canada (TCu-380S)

**Date first marketed:** 1982 (TCu-380A)

**Major distributors:** TCu-380A—Finishing Enterprises, US; P.T. Kimia Farma, Indonesia (trial production); Produtos Medicos Ltda., Brazil; Gyno-Pharma, Inc., US (brand name Para-Gard; sales beginning 1988); TCu-380A and TCu-380S (brand name Gyne T Slimline)—Ortho Canada; TCu-380S—Cilag, France; TCu-380Ag—Leiras Medica, Finland.



**Length:** 36 mm **Width:** 32 mm

**Strings:** Two white (formerly blue)

**Inserter type and diameter:** Withdrawal; 4.4 mm (All use the same inserter tube, but TCu-380S arms fit completely in tube. With TCu-380A and Ag only the tips of the arms fit inside the tube.)

**Approved lifespan:** TCu-380A—US and UK, 4 years; various other European countries, 5 years. TCu-380Ag—Finland, 5 years. TCu-380S—various European countries and Canada, $2^1/_2$ years.

**Areas of major use:** TCu-380A—worldwide except China; available in US in 1988. TCu-380Ag—Finland. TCu-380S—Canada, Western Europe, Hong Kong.

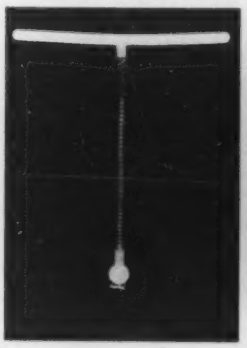
### TCu-200, TCu-200B, and TCu-200Ag

**Description:** Polyethylene with barium sulfate added for visibility on x-rays. 200 $mm^2$ copper wire wrapped around stem. The wire on the TCu-200Ag has a silver core. The TCu-200B (shown) has a ball at the tip of the stem; the TCu-200 does not.

**Developers:** Howard Tatum (US) and Jaime Zipper (Chile)

**Date first marketed:** 1972

**Major distributors:** TCu-200B—Finishing Enterprises, US, and Produtos Medicos Ltda., Brazil; TCu-200—Ortho Canada, and Leiras Medica, Finland; TCu-200Ag—Leiras Medica, Finland



**Length:** 36 mm **Width:** 32 mm

**Strings:** Two; color varies

**Inserter type and diameter:** Withdrawal; 4.4 mm

**Approved lifespan:** US, 4 years; various European countries, 3 years

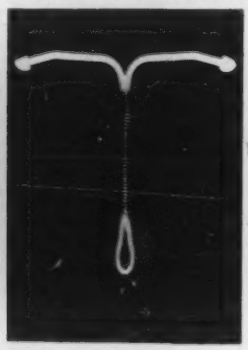
**Areas of major use:** Worldwide except China and US

### Nova T

**Description:** Polyethylene with barium sulfate added for visibility on x-rays. 200 $mm^2$ copper wire with a silver core wrapped around the stem.

**Developers:** Outokumpu Oy (Finland)

**Date first marketed:** 1979



**Major distributors:** Leiras Medica, Finland; A.B. Kabi, Sweden; Schering AG, West Germany.

**Length:** 32 mm

**Width:** 32 mm

**Strings:** Two white

**Inserter type and diameter:** Withdrawal; 3.6 mm

**Approved lifespan:** Various European countries, 5 years

**Areas of major use:** Europe, Canada, Australia, New Zealand

### Lippes Loop

**Description:** Polyethylene with barium sulfate added for visibility on x-rays. Available in four sizes, designated A (left) through D (right).

**Developer:** Jack Lippes (US)

**Date first marketed:** 1962

**Major distributors:** Finishing Enterprises, US; P.T. Kimia Farma, Indonesia (in-country distribution only).

**Length:** A—26.2 mm; B—25.2 mm; C—27.5 mm; D—27.5 mm

**Width:** A—22.2 mm; B—27.4 mm; C—30.0 mm; D—30.0 mm

**Strings:** Two; A—blue, B—black, C—yellow, D—white

**Inserter type and diameter:** Push-out; 4.7 mm

**Areas of major use:** Developing countries except China

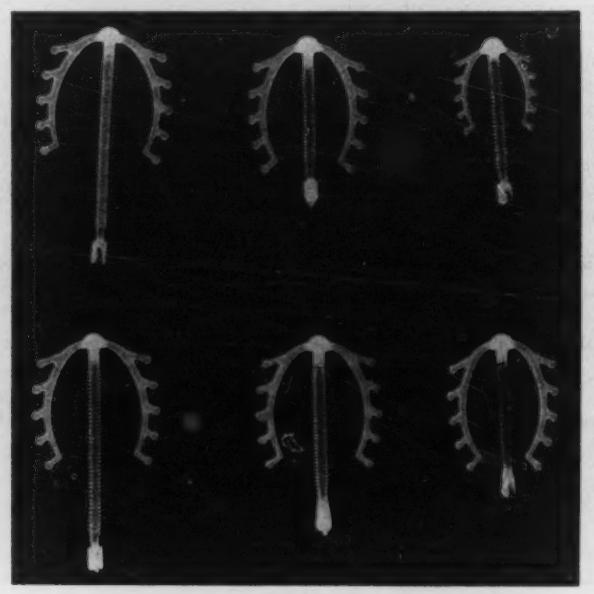
## Multiload-250 (MLCu-250) and 375 (MLCu-375)

**Description:** Polyethylene with two flexible arms with spurs. The MLCu-250 has 250 $mm^2$ copper wire on the stem and is available in 3 sizes (top, left to right)—Standard, Short, and Mini. The MLCu-375 has 375 $mm^2$ copper wire and is available in 3 sizes (bottom, left to right)—Standard, Short, and SL.

**Developer:** W.A.A. van Os (Netherlands)

**Date first marketed:** 1974

**Distributors:** Produced by Multilan AG, Switzerland; Biotechno, Brazil (for in-country distribution only); and P.T. Kimia Farma, Indonesia (trial production). Distributed through subsidiaries and agents of Organon, Netherlands, member of AKZO Pharma Group; Parke-Davis, Italy; Laboratoires CCD, France.



**Length:** Standard (250 and 375)—35 mm; 375SL—29 mm; 250 Short—24 mm; 250 Mini—24 mm

**Width:** Standard (250 and 375), 375SL, 250 Short—18 mm; 250 Mini—13 mm

**Strings:** Two black or colorless

**Inserter type:** Withdrawal (no plunger)

**Insertion diameter:** Standard (250 and 375), 375SL, and 250 Short—12 mm; Mini—9 mm. (Arms remain outside inserter tube.)

**Approved lifespan:** MLCu-250—most European countries, 3 years; MLCu-375—most European countries, 5 years.

**Areas of major use:** Europe; Australia; India; Indonesia and other Southeast Asian countries; New Zealand, Latin America.

## TCu-220C

**Description:** Polyethylene with barium sulfate added for visibility on x-rays. 220 $mm^2$ copper in seven copper sleeves—2 on the arms and 5 on the stem.

**Developer:** Population Council (US)

**Date first marketed:** 1980

**Major distributors:** Laboratorios Alpha, Mexico; Tianjin Medical Instrument Corporation, Factory No. 4, China (in-country distribution only).

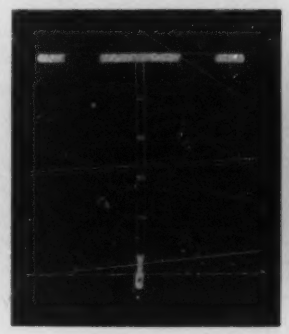
**Length:** 36 mm **Width:** 32 mm

**Strings:** Two

**Inserter type and diameter:** Withdrawal; 4.4 mm

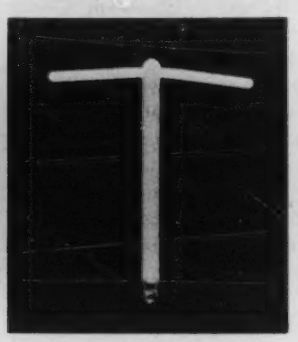
**Approved lifespan:** Mexico, 3 years

**Areas of major use:** China, Mexico



## Progestasert Intrauterine Progesterone Contraceptive System

**Description:** Ethylene vinyl acetate copolymer. Vertical stem contains a reservoir of 38 mg progesterone and barium sulfate (for visibility on x-rays) in silicone oil base. Releases 65 µg progesterone per day.



**Developer:** Alza Corp. (US)

**Date first marketed:** 1976

**Distributors:** Alza Corporation, US; Polcrome Ltd., UK; Theraplix Divison, Rhone Poulenc Santé, France.

**Length:** 36 mm **Width:** 32 mm

**Strings:** Two blue-black

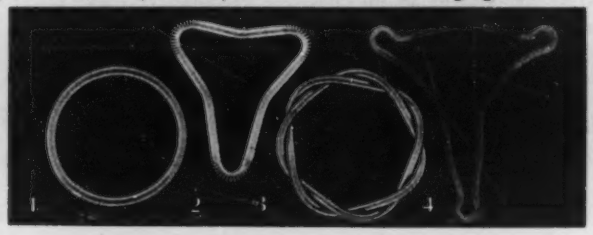
**Inserter type and diameter:** Withdrawal; 8 mm

**Approved lifespan:** US, one year; France,18 months.

**Areas of major use:** US, France

## Chinese IUDs

**Description:** The most widely used IUD in China is the stringless single-coil stainless steel ring (1). The newly developed uterine cavity shaped steel ring is becoming widely used (2). It is replacing the Mahua ring, a double-coil stainless steel ring (3). Much less commonly used is the Shanghai V-200, made of silicone plastic on a wire frame with 200 $mm^2$ copper wire (4).




**Size:** The single-coil ring and the Mahua ring are produced in seven sizes ranging from 18 to 24 mm in diameter.

**Strings:** None on rings or on uterine-shaped device. Two black threads on Shanghai V-200.

**Inserter type:** Stainless steel rod with notch in tip to hold coil

dose—and would be offset by reduced expenses for clinic visits and treating infections. Along with antibiotics, meticulous aseptic technique during insertion can reduce risks of infection (see box, p. 10).

IUDs without strings have also been considered. Findings on IUDs without strings have been mixed, however. On one hand, two laboratory studies of IUDs removed from women reported more bacterial colonization on IUDs with monofilament strings than on IUDs without strings (350, 434). On the other hand, only one (92) of six studies comparing women using IUDs with and without monofilament strings has reported a difference in rates of infection (38, 68, 92, 114, 210, 428). Family Health International is conducting a 5-center randomized study of TCu-200 IUDs with and without strings. Preliminary results show no difference in infection rates (48, 114, 425).

Organon International, manufacturer of the Multiload IUD, has tested coating the MLCu-250 in chlorhexidine acetate, an antiseptic. This does not appear to prevent introduction of microorganisms into the uterus at insertion, however (85).

### IUDs Do Not Prevent AIDS

In contrast to condoms, IUDs provide no protection against AIDS. AIDS—acquired immune deficiency syndrome—is a new and fatal disease that has no cure. It is caused by the human immunodeficiency virus (HIV). No vaccine against this virus has been developed. HIV is found in semen as well as blood. Thus condoms, which prevent semen from entering the vagina, and possibly spermicides, which can kill HIV, can protect against AIDS. Other family planning methods cannot.

To protect against AIDS, all women who are not sure whether they or their partners are infected should use condoms and spermicides during every act of sexual intercourse, just as they would use them to prevent pregnancy. (See **Population Reports**, *AIDS—A Public Health Crisis*, L-6, July-August 1986.) If a woman's partner will not use a condom, she should at least use a spermicide. Any couple living in an area where AIDS or HIV infection has been found and whose sexual relationship has not been a long-term, mutually faithful one is at risk of AIDS. Women who have more than one sexual partner or whose partners have more than one partner are not the best candidates for IUDs in any case. Nonetheless, any such woman using another effective method of family planning to prevent pregnancy should be encouraged to continue it even while she uses condoms and spermicides to prevent AIDS (231). Preventing pregnancy is especially important if a woman or her partner is likely to be infected because HIV can spread from a woman to her fetus during pregnancy.

There has been no research to indicate whether IUDs increase or decrease the chances of HIV transmission or whether IUDs pose any special risk to a woman infected with HIV. Studies to address these questions are planned (140, 438).

There are no reports that HIV has been transmitted to a woman during IUD insertion or that a health care provider has been infected with HIV while inserting an IUD in an infected woman. Still, it is theoretically possible that transmission could occur.

The same clinic procedures that protect both clients and health care providers against other infections can also protect them against HIV infection. To avoid any risk of infecting a client during IUD insertion, providers should see that all instruments are properly disinfected before each use (see box, p. 10). To avoid any risk of transmission from a client to a health care provider, standard procedures for preventing blood-borne diseases such as hepatitis B should be followed. Providers should:

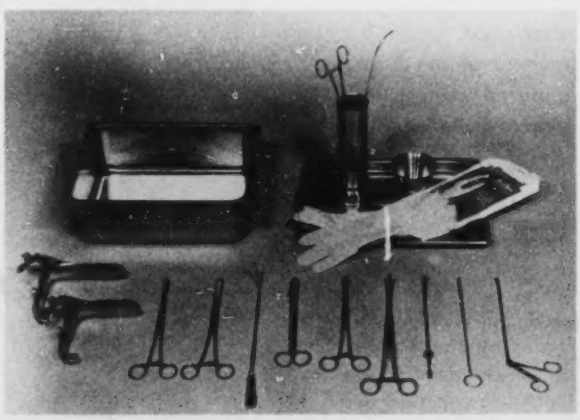
- Wear gloves when they might come in contact with blood, body fluids, or mucous membranes;
- Change gloves after each client;
- Wash hands immediately and thoroughly after any direct contact with blood, body fluids, or mucous membranes;
- Take care to avoid pricking or cutting themselves with a syringe or other instrument that might have blood or body fluid on it; and
- Clean up blood spills with disinfectant immediately (396, 435).

## DISTRIBUTION AND USE

Nearly 85 million women worldwide are using IUDs, according to estimates based on survey results and service statistics (see Tables 2 and 3). About 70 percent of the world's IUD users, or 59 million women, are in China. In most countries that have conducted more than one representative sample survey of contraceptive prevalence, IUD use has remained stable or increased since the 1970s. Where voluntary sterilization and injectable contraceptives are available, however, use of these methods has usually grown faster than IUD use (391).

### Asia and the Pacific

The highest prevalence of IUD use is in China. Almost 30 percent of married women of reproductive age use IUDs (67). IUDs are a favored contraceptive method as part of China's one-child campaign. Couples are thought to be more willing to have only one child if they can use a reversible method, such as the IUD, rather than voluntary sterilization (468). IUD use has declined recently in China, however—from 35 percent in 1982 to just under 30 percent in 1986. Use of male or female voluntary sterilization increased from 25 to 36 percent and is now the predominant method of contraception (66, 67). IUDs are also widely used in several other Asian countries including Taiwan and Indonesia (see Table 3). In Viet Nam and North Korea IUDs are reportedly the leading method of contraception (112, 392, 393). In India IUD use is slight but has increased since 1981 due in part to the government's increased emphasis on reversible contraceptive methods. According to 1985 government estimates based on service statistics, about 4 percent of Indian married women of reproductive age use IUDs (37).



**The IUD backup kit provided by the United States Agency for International Development and cooperating agencies contains all the instruments and equipment needed to insert and remove IUDs.**

In Bangladesh, Hong Kong, South Korea, Sri Lanka, Taiwan, and Thailand, while overall contraceptive prevalence has increased since the 1970s or early 1980s, the percentage of women using the IUD has declined or remained the same. More use of voluntary sterilization and, to a lesser degree, injectable contraceptives accounts for most of the increase in overall use (49, 101, 175, 197, 220, 354, 394).

### Latin America and the Caribbean

In many Latin American and Caribbean countries—Colombia, Costa Rica, Ecuador, Guatamala, Honduras, Mexico, Panama, Paraguay, and Peru—IUD use has increased slightly over the last decade (44, 77, 75, 129, 151, 220, 466, 467). Only in Bolivia, Chile, and Peru, however, are IUDs the most widely used modern method (65, 220, 467). In most Latin American and Caribbean countries voluntary sterilization and oral contraceptives are more commonly used than IUDs. Chile may have the highest level of IUD use in the region. In a 1976 survey 20 percent of married women of reproductive age used IUDs, and use has reportedly increased since. In 1986 an estimated 77 percent of contraceptors were using IUDs (83). IUDs may be widely used partly because voluntary sterilization is not available to most couples in Chile (65, 163, 306). It is illegal except for therapeutic reasons. In Brazil the situation is reversed. Although voluntary sterilization is likewise illegal except for therapeutic reasons, in fact it is widely used—by 28 percent of couples. The prevalence of IUD use in Brazil, at one percent, is among the lowest in the region (306, 345). Until the mid-1980s Brazil prohibited making or importing IUDs (319).

**Table 2. Estimated Number of IUD Users Worldwide, 1987**

| Region & Country | % of MWRA* Using IUDs | No. of Women (in 1,000s) |
|---|---|---|
| AFRICA | 0.7 | 500 |
| ASIA & PACIFIC | | |
| China | 29.3 | 59,000 |
| Indian subcontinent | 2.4 | 4,200 |
| Other Asia & Pacific | 7.1 | 5,800 |
| All Asia & Pacific | 14.9 | 69,000 |
| LATIN AMERICA & CARIBBEAN | | |
| Brazil | 1.0 | 200 |
| Other | 6.0 | 2,100 |
| All | 4.1 | 2,300 |
| NEAR EAST & NORTH AFRICA | 5.0 | 1,600 |
| DEVELOPED | | |
| Scandinavia | 21.0 | 600 |
| Other Europe | 7.5 | 7,900 |
| US & Canada | 5.0 | 1,800 |
| Australia & New Zealand | 5.0 | 150 |
| Japan | 4.0 | 700 |
| All | 6.7 | 11,150 |
| TOTALS | | |
| Developing countries except China | 2.7 | 14,400 |
| Developed countries | 6.7 | 11,150 |
| World, except China | 3.8 | 25,550 |
| China | 29.3 | 59,000 |
| World | 10.3 | 84,550 |

*Married women of reproductive age

Sources: World Fertility Surveys, Contraceptive Prevalence Surveys, Demographic and Health Surveys, other national surveys, and service statistics, extrapolated to population estimates from Population Reference Bureau (143, 205) and Nortman (259)

**Table 3. Percentage of Married Women, Age 15–44, Using IUDs, as Reported in Selected Sample Surveys,* 1977–1987**

| Region/ Country | Ref. No. | Date of Survey | % Using Any Method[a] | % Using IUD | % of Contraceptors Using IUDs |
|---|---|---|---|---|---|
| AFRICA | | | | | |
| Botswana | 220 | 1984 | 29 | 5 | 17 |
| ASIA & PACIFIC | | | | | |
| China | 66 | 1982 | 69[b] | 35[b] | 50[b] |
| Indonesia | 157 | 1985 | 38[c] | 12 | 31 |
| Korea, Rep. of | 394 | 1982 | 57 | 7 | 12 |
| | 197 | 1985 | 70 | 7 | 11 |
| Taiwan | 49 | 1980 | 70 | NA | 32 |
| Thailand | 175 | 1984 | 65 | 5 | 8 |
| LATIN AMERICA & THE CARIBBEAN | | | | | |
| Colombia | 220 | 1978 | 48 | 8 | 16 |
| | 75 | 1986 | 63[b] | 10[b] | 16[b] |
| Costa Rica | 220 | 1978 | 65 | 5 | 7 |
| | 77 | 1986 | 71[e] | 8 | 12 |
| Ecuador | 220 | 1979 | 35 | 5 | 15 |
| | 47 | 1987 | 44[b] | 10[b] | 22[b] |
| Mexico | 220 | 1979 | 40 | 7 | 16 |
| Montserrat | 171 | 1984 | 53[a,e] | 11[a] | 21[d] |
| Panama | 129 | 1984 | 59[d] | 6 | 10 |
| Paraguay | 466 | 1987 | 38[d] | 5 | 14 |
| Peru | 467 | 1986 | 46[b] | 7[b] | 16[b] |
| Venezuela | 220 | 1977 | 49 | 9 | 17 |
| NEAR EAST & NORTH AFRICA | | | | | |
| Egypt | 315 | 1984 | 30[b] | 8[b] | 28[b] |
| Jordan | 220 | 1983 | 26[e] | 9 | 34 |
| Tunisia | 220 | 1978 | 32 | 9 | 29 |
| | 220 | 1983 | 42 | 15 | 36 |
| Turkey | 388 | 1983 | 62 | 9 | 14 |
| DEVELOPED COUNTRIES | | | | | |
| Austria | 245 | 1978 | 84 | 5 | 6 |
| | | 1981–82 | 82 | 9 | 11 |
| Belgium (Flemish) | 408 | 1984 | 79 | 10 | 8 |
| Czecho-slovakia | 26 | 1977 | 95 | 18 | 19 |
| Finland | 26 | 1977 | 80 | 29 | 36 |
| Germany, West | 87 | 1985 | 86 | 15 | 17 |
| Hungary | 155 | 1986 | 73 | 19 | 26 |
| Netherlands | 404 | 1982 | 78[d] | 10[d] | 13[d] |
| Norway | 26 | 1977–78 | 71 | 28 | 39 |
| Spain | 349 | 1985 | 64 | 7 | 10 |
| Sweden | 365 | 1980 | 62 | 17 | 27 |
| Switzerland | 153 | 1980 | 70 | 11 | 16 |
| UK (England, Scotland & Wales) | 390 | 1983 | 83[d] | 7[d] | 8[d] |
| US | 220, 242 | 1982–83 | 68 | 5 | 7 |

*Includes only countries where 5 percent or more of married women of reproductive age used IUDs. All numbers rounded to whole numbers. DEVELOPING COUNTRIES: Among currently married women age 15–45 except: Indonesia 1985, 10–49; Taiwan, percentage using any method is among married women 22–39, percentage of contraceptors using IUDs is among all women 15–39; Turkey, age <50, fecund, nonpregnant. DEVELOPED COUNTRIES: Among currently married, women below age 45, except: Austria, women married 1974–77; Belgium 1984, excludes women who intend to be pregnant within a year; Hungary, age <40, excludes users of voluntary sterilization; Netherlands, women born 1945–64; Spain 1985, age 18–49, excludes users of voluntary sterilization; Sweden, all women age 20–44, excludes users of voluntary sterilization; US, excludes women in Alaska, Hawaii, and institutions.

[a]Includes traditional methods (breastfeeding, douche, abstinence, folk) except where noted

[b]Currently married age 15–49

[c]Not indicated whether traditional methods included

[d]Includes women in union

[e]Excludes traditional methods

### Middle East and North Africa

In Egypt, Jordan, Tunisia, and Turkey, IUD use has increased since the 1970s (220, 315, 388). The rise in IUD use explains most of the increase in overall contraceptive prevalence in these countries except in Turkey, where an increase in withdrawal was more important (388). IUDs and oral contraceptives are the most widely used modern methods of contraception. More than one-quarter of contraceptors in Egypt, Jordan, and Tunisia rely on IUDs (see Table 3). Voluntary sterilization is uncommon except in Turkey (220, 239, 315, 388).

### Sub-Saharan Africa

In sub-Saharan Africa levels of IUD use are generally the lowest in the world, as are overall contraceptive use rates. In most surveyed countries less than 0.5 percent of married women of reproductive age use IUDs (220, 311). Assessing trends in IUD use in sub-Saharan Africa is difficult because few countries have conducted more than one survey. Family planning program statistics from The Gambia, Mauritius, Mozambique, and Sierra Leone and surveys in Kenya suggest that IUD use in these countries is increasing (180, 259).

**Table 4. Deliveries of IUDs by Major Donor Agencies, 1982–1987 (in 1,000s)**

| Recipient Region & Donor | 1984 | 1985 | 1986 | 1987 |
|---|---|---|---|---|
| AFRICA | | | | |
| US AID | 290 | 216 | 179 | 117 |
| IPPF | 22 | 47 | 68 | 32 |
| UNFPA | 218 | 16 | 55 | 72 |
| FPIA | 103 | 105 | 85 | 61 |
| Pathfinder* | 7 | 9 | 17 | 43 |
| WHO | NA | — | — | 15 |
| Subtotal | 640 | 393 | 404 | 340 |
| ASIA & PACIFIC | | | | |
| US AID | 318 | 1,670 | 1,286 | 545 |
| IPPF | 23 | 5 | 62 | 72 |
| UNFPA | 5,565 | 20 | 4,270 | 6,133 |
| FPIA | 158 | 810 | 144 | 56 |
| Pathfinder* | 4 | 0 | 0 | 0 |
| WHO | NA | 1,350 | 1,200 | 391 |
| Subtotal | 6,068 | 3,855 | 6,962 | 7,197 |
| LATIN AMERICA & CARIBBEAN | | | | |
| US AID | 1,074 | 3,165 | 2,199 | 1,383 |
| IPPF | 126 | 143 | 151 | 3 |
| UNFPA | 101 | 18 | 30 | 42 |
| FPIA | 143 | 92 | 503 | 317 |
| Pathfinder* | 59 | 63 | 105 | 54 |
| PAHO | 141 | 723 | 84 | 77 |
| Subtotal | 1644 | 4,204 | 3,072 | 1,876 |
| NEAR EAST & NORTH AFRICA | | | | |
| US AID | 503 | 50 | 489 | 685 |
| IPPF | 34 | 10 | 32 | 26 |
| UNFPA | 39 | 45 | 51 | 2 |
| FPIA | 343 | 238 | 163 | 199 |
| Pathfinder* | <1 | <1 | 15 | 4 |
| Subtotal | 919 | 343 | 750 | 916 |
| AGENCY TOTALS | | | | |
| US AID | 2,184 | 5,101 | 4,154 | 2,730 |
| IPPF | 204 | 206 | 313 | 132 |
| UNFPA | 5,926 | 100 | 4,406 | 6,249 |
| FPIA | 747 | 1,245 | 894 | 632 |
| Pathfinder* | 70 | 73 | 136 | 101 |
| WHO | NA | 1,350 | 1,200 | 406 |
| PAHO | 141 | 723 | 84 | 77 |
| Total | 9,270 | 8,797 | 11,187 | 10,326 |

**Note:** Excludes small quantities sent to Europe by WHO and UNFPA or sent as samples or for research. Quantities listed for FPIA, IPPF, and Pathfinder include only IUDs purchased with non-US AID funds. IUDs purchased by US AID and shipped by FPIA, IPPF (which received US AID supplies through 1985), and Pathfinder are included with US AID deliveries.

*For fiscal years, July 1-June 30

Sources: US Agency for International Development (US AID) (29), International Planned Parenthood Federation (IPPF) (110, 166), United Nations Fund for Population Activities (UNFPA) (417), Family Planning International Assistance (FPIA) (278), Pathfinder Fund (Pathfinder) (189), World Health Organization (WHO) (256), Pan American Health Organization (PAHO) (347)

### Developed Countries

IUDs are most widely used in Scandinavia, France, and some Eastern European countries. In France, Hungary, Norway, and Finland, about one-quarter or more of married women of reproductive age rely on IUDs (297) (see Table 3). Use is lower in Canada, the US, Australia, New Zealand, and Japan, however, where only about 5 percent or less of married women of reproductive age use IUDs (43, 187, 192, 220, 242, 324, 325). IUD use has leveled off or declined in the US, the UK, and many other developed countries (181, 242, 263, 295, 324, 325, 390). This is partly because voluntary sterilization has become widely available and popular among older women (52, 182, 242, 324, 390). Also, publicity surrounding the withdrawal of the Dalkon Shield from the market and subsequent lawsuits in the US have deterred some women from using any IUD and have made doctors more cautious about offering IUDs to younger women (156, 368).

### Donor Agency Supplies

Major donor agencies, particularly the United States Agency for International Development (US AID) and the United Nations Population Fund (UNFPA), supply most of the IUDs used in developing countries other than China. In 1987 donor agencies distributed more than 10 million IUDs to about 75 countries. India has received the largest share of IUD donations in recent years—some 6 million in 1987. In Asia, Bangladesh and Viet Nam also have been major recipients. Elsewhere, major recipients have been Mexico and Colombia in Latin America; Turkey and Egypt in North Africa and the Near East; and Kenya in sub-Saharan Africa.

Donor agencies have shifted away from the Lippes Loop and other unmedicated devices since the early 1980s and now supply mostly copper IUDs. For most recipients there has also been a marked shift from the TCu-200 to the TCu-380A. In 1987 US AID began supplying only the TCu-380A—a decision based on its greater effectiveness (401). A major exception has been India, which has requested the TCu-200.

Through agreements between The Population Council, which licenses the copper T IUDs, and the manufacturers, these IUDs are available at special low prices to government and nonprofit family planning programs. The cost of IUDs purchased in large quantities by US AID or other public sector organizations is at most $0.30 (US) for the Lippes Loop, $0.75 for the TCu-200, and $1.00 for the TCu-380A (36, 321, 417). Assuming that these IUDs are used for at least one year, the annual cost compares favorably with the annual cost to donors for many other contraceptive methods: about $1.80 for combined estrogen-progestin oral contraceptives; $4.00 for depot medroxyprogesterone acetate (DMPA) injectable; and $2.80 for Norplant. At $0.45, however, the cost for a one-year supply of 100 condoms is less (217, 321).

### IUD Manufacturing

IUDs are made in the US, Canada, Brazil, China, Indonesia, Mexico, Viet Nam, and several European countries. Generally, copper T IUDs are manufactured under license from the

Population Council. The licensees are commercial firms except in China and Indonesia, where they are governmental organizations (282). In China, where stainless steel rings and other unmedicated IUDs have been produced for many years, production of the TCu-220C began in 1983. One factory manufactured more than 2 million in 1987. A second factory is scheduled to open in late 1988 (240, 469). In Indonesia manufacturing of the TCu-380A began in 1987 and the MLCu-250 is currently in trial production. Lippes Loops have been produced in Indonesia since 1975, and current production meets in-country demand (310, 362). In Brazil the MLCu-250, TCu-200B, and TCu-380A are made. Most of the copper Ts are exported to other Latin American countries and to Asia and Africa. The MLCu-250s are for local use (80, 238). In Mexico the TCu-220C has been manufactured for local use since 1974 (309).

## IUDS IN FAMILY PLANNING PROGRAMS

The safety, effectiveness, and acceptability of the currently available IUDs depend partly on the device itself but even more on the quality of IUD services. For the best outcome, family planning programs must provide:

- Careful selection of users,
- Informative and empathetic counseling,
- Practical clinical training for health care providers, and
- Regular follow-up care and back-up medical care in case of complications.

Family planning programs should offer IUDs along with other methods of contraception. Then clients can choose the method that best suits them.

### Screening Potential IUD Users

The IUD is a safe and effective contraceptive method for many women. Like any other method, however, it is better suited for some women than others.

Health care providers must be familiar with all relative and absolute contraindications to IUD use (see box, p. 24). To identify medical contraindications, the health care provider should take a medical history, perform a pelvic exam, check for signs of anemia, and, where possible, do lab tests for sexually transmitted diseases. If lab tests are not available or if it is not feasible to wait for test results, at a minimum all clients should be carefully evaluated for clinical signs of sexually transmitted diseases (395, 398) (see box, p. 23). As part of the counseling process (see below), the health care provider also should ask whether the woman plans to have children in the future and whether she and her partner have a mutually faithful sexual relationship. In areas where sexually transmitted diseases are common, health care providers should be especially cautious in screening clients.

### Counseling

Counseling is an essential part of every family planning provider's role. Informative and empathetic counseling helps clients make the best choice of a contraceptive method and helps them use the method safely, effectively, and with satisfaction (see **Population Reports**, *Counseling Makes A Difference*, J-35, November 1987).

There are six elements to family planning counseling (see **Population Reports**, *Counseling Guide*, J-36, December 1987). The provider can remember the steps using the English word "GATHER."

#### "GATHER"

**G—Greet clients**. The provider should greet clients politely and give them full attention.

**A—Ask clients about themselves**. The provider should ask clients about their family planning needs and obtain background information and a brief medical history.

**T—Tell clients about family planning methods.** The provider should list the available family planning methods and clearly describe those that interest the client—how they work, advantages and disadvantages, and possible side effects. Even clients who immediately express a preference for the IUD need to know what other methods are available.

**H—Help clients choose a method**. Some women may have already decided that they want an IUD. Others may want advice and guidance from the provider. In either case the provider should help the woman decide on a safe method that suits her needs and plans. If the method is contraindicated, the provider should explain why and help the client select another method. If there are relative contraindications, the provider and client should compare the risks and benefits of the IUD and of other contraceptive methods. The effectiveness of various methods should be discussed in light of the risks and problems of an unintended pregnancy. The final decision to use an IUD—or any other method—must be an informed choice by the client.

**E—Explain how to use the IUD.** Once a woman decides to use an IUD, the provider should explain:

- When, where, and how it will be inserted,
- The common side effects,
- The slight chance of more serious complications, expulsion, or unintended pregnancy,
- The warning signs of serious complications.

Women who understand that mild cramping and bleeding in the days following insertion and heavier menstrual periods while using an IUD are common and usually harmless will be less likely to have their IUDs removed unnecessarily (184, 353). A study in Sri Lanka, for example, found that women who were counseled by specially trained midwives and satisfied IUD users had side effects similar to those among women who received no special counseling. Nevertheless, the women who received special counseling kept their IUDs longer (353).

It is helpful for the provider to use a checklist of important points the IUD user needs to know. The checklist helps make sure that no important information is left out (see box, p. 25). To help the client understand and remember the most important points, the provider should explain them clearly and simply and go over them several times. It is also helpful to give clients printed material to take home, including a card with the name and picture of the IUD, noting the date of insertion and time for removal (398) (see p. 24). She should also be told if and how she will be notified when it is time for the IUD to be replaced. Of course, the family planning program should keep records for each IUD user showing the type of IUD and when it was inserted. These records should be used to answer questions from women who have forgotten when to have their IUDs replaced and to follow up users when the time for replacement approaches.

**R—Return for follow-up.** When a woman has an IUD inserted, she and the provider should plan for a follow-up visit within three months. She should understand, however, that she can return at any time if she has questions or problems or wants

# Research on New IUDs

Researchers are seeking to develop new IUDs that are as effective as current IUDs but have lower rates of expulsion and side effects. Several approaches are being considered.

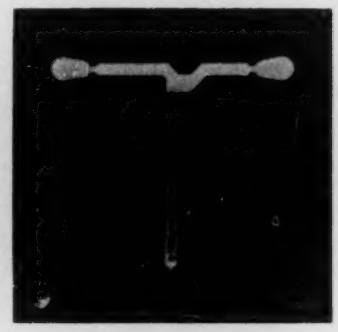
### Modified and New Copper and Unmedicated IUDs

Two modified versions of the MLCu-375, called the Multiload Mark II (see photo) and the MLCu-375 SL, are in clinical trials. The Mark II is designed to reduce problems with insertion and removal. Unlike other Multiload devices, which are inserted with both arms outside the inserter tube, the Mark II is inserted entirely through an inserter tube. Also, the arms of the Mark II are shorter and more flexible. The MLCu-375 SL has a shorter vertical stem. It is intended for the woman with a short uterus, as well as for the woman with average uterine length. The MLCu-375 SL is marketed in Finland (79, 411).

**Multiload Mark II**

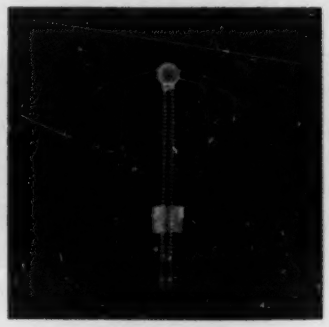
Several modifications of copper T IUDs are being studied. In China researchers have developed a smaller TCu-220C because they think that the standard TCu-220C is too large for Chinese women. Both the stem and horizontal arms of the T are shorter, and the stem holds a total of 188 $mm^2$ of copper in four rather than five copper sleeves. Hence the IUD is called the TCu-188. Clinical trials are underway involving about 1,000 women in seven clinics (25).

Researchers in Switzerland are testing a copper T that has a soft silastic ball at the tip of each arm, designed to block the openings to the fallopian tubes. This design is intended to minimize the risk of ectopic pregnancy and perforation (88). The developers call it the uterine-occluding device (see photo).



**Uterine-Occluding Device**

Two new copper devices, the Ombrelle and the Fincoid-350, are being studied in Europe. Both are designed to be flexible and to move toward the uterine fundus when the uterus contracts. This is intended to reduce expulsion and minimize bleeding and pain (150, 158, 406). Preliminary trials have found low rates of pregnancy, expulsion, and removal for bleeding and pain (14, 16, 406). A multicenter randomized trial comparing the Ombrelle-380 and the Nova T is underway (406). The Ombrelle-250 has been marketed in France since 1986 (14) (see photo). The only randomized trial to date of the Fincoid-350 found rates of expulsion and removal for bleeding and pain no lower than with the MLCu-375 and the Nova T (314) (see Table 1).



**Ombrelle 250**

A "uterine-shaped" IUD made of a single coil of stainless steel has been developed and is being used in China (see photo, p. 17). The shape is intended to minimize expulsions. An ongoing study found one-year expulsion and pregnancy rates lower than with the standard Chinese stainless steel ring. A version with copper bands inside the coil is now being tested (25).

### Hormone-Releasing IUDs

The Population Council and Leiras Medica in Finland have been testing IUDs that release levonorgestrel, a synthetic hormone of the progestin family. The IUD, called the LNG-20, contains 46 to 60 mg of levonorgestrel and releases it at a rate of 20 µg per day. Extensive trials show very low pregnancy rates—less than 0.5 per 100 women after one year of use (224, 280, 335). The rate of discontinuation for bleeding problems is higher than with other IUDs, however, because about 25 percent of users develop amenorrhea or very scanty bleeding (335). The LNG-20 IUD is currently being redesigned because one component of the steroid reservoir is no longer available.

### Frameless IUDs

Two IUDs without rigid frames are being tested in several countries (407, 412). The CuFix-360 consists of six copper sleeves—a total of 360 $mm^2$ copper—strung on a surgical nylon (polypropylene) thread knotted at one end (374). During insertion the knot is pushed into the muscle of the fundus with a needle inserter. Preliminary tests in Belgium found no pregnancies in over 700 women during the first 12 months. Rates of expulsion and of removals for pain and bleeding were 0.8 and 1.3 per 100 women, respectively (407).

The Fundus Fixing Reversible Sterilization is described by its developers not as an IUD but as reversible sterilization with a uterine implant (221). It has a design like that of the CuFix-360. Instead of copper sleeves, however, it carries 400 $mm^2$ copper wire coiled around two nylon threads. The device is attached to the fundal wall with a miniature stainless steel spring fastener like those used with cardiac pacemakers. The device is removed by unscrewing the fastener. It does not have a string. Clinical trials are underway in Egypt, Tunisia, and the Netherlands (412).

the IUD removed (319, 398). Also, she should return as soon as possible if she notices any warning signs (see box, p. 25).

The purpose of routine follow-up visits is to:

- Reassure the client about any common side effects and address any other concerns or questions;
- Check that the IUD is in place;
- Diagnose any complications and start treatment;
- Remind women of the warning signs of IUD complications.

At each follow-up visit the provider should take a clinical history, paying special attention to menstrual problems, pain, and possible pregnancy or expulsion. A pelvic examination should be performed not only to check for the IUD strings but also to look for signs of pelvic infection (7, 82, 436).

Especially where regular follow-up is not feasible, the provider should be sure that the woman knows when and where to seek medical care (164). Also, community health workers can visit women at home and refer them to more skilled health workers if necessary (436).

To handle serious complications, programs should make arrangements with a referral medical center. The center should be staffed with surgeons and gynecologists and have facilities for diagnostic and surgical procedures (436).

Health care providers should remove copper IUDs every three to five years, depending on the approved lifespan (see box, p. 6). If a woman is having no problems, the Lippes Loop and other nonmedicated IUDs do not need to be removed until menopause (7, 162). After menopause removal may be difficult because the uterus shrinks and narrows (179). Of course, removal should be available promptly whenever a woman requests it and whatever her reason.

When the TCu-380A is being introduced, women using a different IUD may want to replace it with the new IUD. Because most IUD complications and pregnancies are most common just after insertion, changing IUDs unnecessarily should be discouraged. A woman should be encouraged to wait and get a TCu-380A when her current IUD reaches the end of its approved lifespan or if her current IUD must be removed for other reasons.

### Training for Health Workers

Safe and effective IUD use requires competent and well-trained health care providers. To be effective, training must include practical experience in performing pelvic exams, IUD insertions, and removals (319, 436). The World Health Organization (WHO) advises that most trainees need to perform at least 50 to 60 pelvic examinations and 10 to 15 IUD insertions under supervision before they have the skill and self-confidence to practice alone (126). The program should be flexible, however, to allow for as many insertions as needed. Training should also emphasize the management of side effects. Practical training should be done in small groups to assure adequate supervision (126, 287). When health care providers return to their jobs, they need to continue inserting and removing IUDs regularly in order to keep up their skills (287, 319). The TCu-380A is inserted just like the TCu-200. Thus no additional training should be needed for health care providers experienced with the TCu-200. Providers who have inserted only Lippes Loops may need instructions on how to insert the TCu-380A.

Special training is needed for postpartum IUD insertion. IUDs are usually inserted with ring forceps or by hand rather than with the standard inserter (71). In the Mexican social security system, Instituto Mexicano del Seguro Social, delivery room staff are trained to insert IUDs, and women are counseled during prenatal care about postpartum contraceptive options. IUDs are the most popular method of postpartum contraception in Mexico (99).

Thorough training in IUD insertion along with careful counseling and follow-up lead to longer IUD use. In areas of Sri Lanka where doctors and public health midwives received refresher training that emphasized insertion technique, counseling, and follow-up, rates of discontinuation due to expulsion or complications were significantly lower than where there was no special training (107, 353).

## *Clinical Signs of Genital Infections*

An IUD should not be inserted in a woman with certain lower genital tract infections—acute mucopurulent cervicitis (inflammation of the cervix with pus and mucus discharge), gonorrhea, chlamydia, and, some suggest, nonspecific vaginitis (also called bacterial vaginosis) (419, 458). Also, an IUD should not be inserted in a woman with suspected pelvic inflammatory disease (126, 398, 419, 437). All potential IUD users should be screened for at least the clinical signs and symptoms of these infections. Where laboratory facilities are available, women may also be given lab tests. Since gonorrhea and chlamydial infection are often asymptomatic in women, family planning providers should also ask a woman if her sexual partner has symptoms. The common clinical signs and symptoms of these infections include:

### Signs and Symptoms in Women

**Lower Genital Tract Infections:**

- Discharge (from the cervix or urethra) containing pus and mucus
- Difficult or painful (burning) urination

**Pelvic Inflammatory Disease:**

- Lower abdominal or pelvic pain
- Painful sexual intercourse, sometimes with bleeding
- Heavy or painful menstruation
- Bleeding between menstrual periods
- Pain on manipulation of the uterus or cervix during pelvic exam
- Body temperature of 38°C (100°F) or higher
- Tenderness or swelling in the area of either fallopian tube or ovary

### Signs and Symptoms in Men

**Gonorrhea, Chlamydial or Other Infection:**

- Discharge from the penis containing pus and/or mucus
- Painful (burning) urination

Sources: Hatcher et al. (142), US CDC (395, 398, 399)

# *Choosing an IUD*

**Family planning providers can use the following checklists to help clients decide whether the IUD is the right method for them.**

**The IUD may be an *appropriate method* for a woman with one or more of these characteristics:**

- ❑ Has trouble using barrier methods or remembering to take a pill every day and wants a method with no bother
- ❑ Does not want more children
- ❑ Already has children and does not want another soon
- ❑ Is in a long-lasting, mutually faithful sexual relationship
- ❑ Cannot use hormonal methods because she has high blood pressure, diabetes, or severe headaches
- ❑ Smokes cigarettes
- ❑ Has successfully used an IUD in the past
- ❑ Is breastfeeding

**The IUD *should not be the first choice* for a woman with any of these relative contraindications:**

- ❑ Has painful or long menstrual periods
- ❑ Is not in a long-lasting, mutually faithful sexual relationship
- ❑ Wants children but has none
- ❑ Has had an ectopic pregnancy
- ❑ Is very anemic
- ❑ Has medical conditions that make an internal infection especially risky: rheumatic heart disease or treatment with steroids or other drugs that suppress the immune system
- ❑ Has fibroids or other conditions that change the shape of the uterus or cervix
- ❑ Has had repeated genital infections

**The IUD *should not be used* by a woman with any of these absolute contraindications:**

- ❑ Has an active or recent genital infection (gonorrhea, chlamydial infection, mucopurulent cervicitis, pelvic inflammatory disease)
- ❑ Has had pelvic inflammatory disease more than once*
- ❑ May be pregnant
- ❑ Has abnormal vaginal bleeding, abnormal cervical smear, or other signs of genital cancer

*If the client really wants an IUD, her case can be individually evaluated based on factors such as how recently she had PID.

Sources: **Population Reports**, *Counseling Guide*, J-36, December 1987. Also, ACOG (7), Burnhill (42), Hutchings et al. (156), Snowden (341), Tatum & Connell (368), WHO (437)

**Front**

**YOUR IUD IS A**

**TCu-380A**

User's Name: _____

Please come for your next visit on: _____/ _____/ _____/ _____/ _____

Friendly Family Planning Clinic

Date IUD inserted: _____

Return for IUD removal on: _____

Yourtown, Anywhere

Telephone: 99-0000

Open Monday-Friday, 9-12 a.m.; 4-7 p.m.

Saturday, 9-12 a.m.

**Back**

**WARNING SIGNS FOR IUD USERS**

You should see a health worker immediately if you have:

**P** – Period late (pregnancy), abnormal spotting or bleeding

**A** – Abdominal pain, pain with intercourse

**I** – Infection (such as gonorrhea), abnormal discharge

**N** – Not feeling well, fever, chills

**S** – Strings missing, shorter or longer

**Prototype Information Card for the IUD User**

**The role of nurses, midwives, and paramedics**. In the US, Sweden, China, Chile, Ecuador, Thailand, Turkey, Ghana, Nigeria, and many other countries, nurses, midwives, or paramedical workers routinely insert IUDs (51, 203, 268, 270, 351, 429, 436, 448). Studies in a number of countries have found that with appropriate training these health care personnel provide safe and effective IUD services (18, 35, 268, 293, 313, 353, 436, 439, 448). A WHO study in the Philippines and Turkey, for example, found that assistant nurse-midwives and doctors were equally able to identify contraindications to and complications of IUD use. Furthermore, rates of expulsion, pregnancy, medical removal, and continuation were similar in the two groups of clients (439). A recent Brazilian study also found no significant differences in complication or continuation rates between women randomly assigned for IUD insertion to a doctor or to a nurse (35).Where nurses, midwives, or paramedical workers provide IUD services, doctors should be readily available for supervision, consultation, and, when necessary, diagnosis and treatment of complications.

Community health workers, traditional midwives, and other briefly trained health workers also can play an important role in IUD services. With appropriate training they can tell women about IUDs and other methods and help in counseling about routine side effects, detecting complications, and referring women for medical care when necessary (125, 436). Satisfied IUD users can also be helpful in spreading the word about IUDs. In Sri Lanka where midwives were teamed with satisfied IUD users, they recruited an average of two-thirds more new clients than midwives alone (107, 353).

Now that long-lasting second-generation copper IUDs are becoming available and research has identified the appropriate users, attention is focusing more on improving the way that programs provide IUDs. As with all family planning methods, it is essential to help the client decide whether the IUD suits her needs or, if the IUD is not medically appropriate, to encourage her to choose another method. At the same time, well-trained providers are needed to insert and remove IUDs properly and to help whenever the user has a problem. When the right women are using IUDs with the right program support, the result is effective, safe contraception and satisfied users.

## New Sources of Information About IUDs

**IUDs: Guidelines for Informed Decision-Making and Use**, developed jointly by the US Centers for Disease Control and the US Agency for International Development, is intended to help policy-makers and program directors plan training and information activities (398).

The booklet in English is available free of charge from: Research Division, Office of Population, US Agency for International Development, Washington, D.C. 20523, USA. A Spanish translation is available from: Development Associates, 2924 Columbia Pike, Arlington, Virginia 22204, USA. A French translation is available from: Ronco Consulting Corporation, 1821 Chapel Hill Road, Durham, North Carolina 27707, USA.

**Mechanism of Action, Safety, and Efficacy of Intrauterine Devices**, World Health Organization (WHO) Technical Report Number 753, is a comprehensive and up-to-date review of the scientific evidence about IUDs. It is available from WHO representatives or appointed booksellers in many countries or from: WHO, Distribution and Sales Service, 1211 Geneva 27, Switzerland. The cost is 12 Swiss francs. Reduced prices are available for purchasers from developing countries (437).

## Ten Important Points to Tell the IUD User

Counseling women about common side effects and problems with IUDs and the warning signs of severe complications promotes safe, effective, and continued use. In particular, the user know and be able to repeat the first two points. The provider should tell the IUD user:

1. That she should **see a health care provider immediately** at the first sign of pregnancy or of pelvic infection. The word "**PAINS**" can help the IUD user remember the warning signs of pregnancy or pelvic infection.

   **P** –Period late (pregnancy), abnormal spotting or bleeding

   **A** –Abdominal pain, pain with intercourse

   **I** –Infection (such as gonorrhea), abnormal discharge

   **N**–Not feeling well, fever, chills

   **S** –Strings missing, shorter or longer
2. She should **come back** to see the provider in about three months for a check-up, even if she does not have any problems. The provider should make an appointment for this follow-up visit.
3. **Menstrual periods will probably be heavier and last longer.** This is usually not harmful. She should see a provider, however, if the bleeding lasts twice as long as her normal menstrual period or if she has to use twice as many pads.
4. What kind of IUD she has and **when it needs to be replaced**. The provider should give her a card showing this information (see figure, p. 24).
5. An IUD offers **no protection against sexually transmitted diseases, including AIDS**. If she does not have a long-term, mutually faithful sexual relationship, she should use condoms to protect herself against sexually transmitted diseases. Using spermicides is not as good as using condoms, but it is better than nothing. Using a condom and spermicide together probably offers the best protection.
6. **She should check the strings** at least during the first three months after insertion, preferably just after each menstruation.
7. **If she gets pregnant, the IUD has to be removed** as soon as possible.
8. **Only a trained health worker should treat problems** with the IUD or remove it.
9. **She can have the IUD removed at any time** for any reason and choose another contraceptive method.
10. **She can have sex as usual**. If the strings bother her husband, they can be cut shorter at the clinic.

Sources: **Population Reports**, *Counseling Guide*, J-36, December 1987; Burnhill (42); Hatcher et al. (142); Tatum & Connell (368); US DHHS (398); WHO (437)

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